

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

STATE OF NEW YORK, et al.,

Plaintiffs,

v.

UNITED STATES DEPARTMENT
OF HEALTH AND HUMAN
SERVICES, et al.,

Defendants.

19 Civ. 4676 (PAE) (lead)

19 Civ. 5433 (PAE) (consolidated)

19 Civ. 5435 (PAE) (consolidated)

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR
SUMMARY JUDGMENT, IN OPPOSITION TO DEFENDANTS' MOTION TO
DISMISS OR FOR SUMMARY JUDGMENT, AND REPLY IN SUPPORT OF
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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Plaintiffs cite the following short form citations for motions, memoranda of law, and exhibits filed in these consolidated cases (all citations to docket entries are to the docket of the lead action, 19 Civ. 4676 (PAE), unless otherwise specified):

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INTRODUCTION

Plaintiffs filed this action to challenge a regulation issued by the U.S. Department of Health and Human Services that—ostensibly in the name of conscience-protection rights—would instead dramatically disrupt the country’s entire health care sector by redefining the scope and application of nearly thirty federal statutes, and that would coerce Plaintiffs to carry out the federal government’s current policy agenda by subjecting Plaintiffs to the unilateral termination of billions of dollars in federal funds under deeply unclear criteria.

1. Judicial review is warranted now. Defendants argue that Plaintiffs’ constitutional claims may not proceed until after the regulation takes effect and the Department initiates a specific enforcement action for noncompliance. But this argument ignores the fact that the purpose and likely effect of the Final Rule is to compel Plaintiffs and others to comply with the Final Rule’s unlawful and unreasonable expansion of federal funding statutes. That compliance obligation ripens on November 22, 2019, the effective date of the Final Rule; and, in the meantime, the Final Rule is already affecting Plaintiffs in significant ways, as the Department expected would occur. No further factual development is needed for the Court to discern the clear constitutional violations at issue, and Plaintiffs would be irreremediably harmed by delay.

In the face of Plaintiffs’ overwhelming showing of drastic and immediate injury—supported by sworn testimony from dozens of national leaders in their fields, with deep experience in medical practice, ethics, public health, epidemiology, health systems administration, and other specialties—Defendants have failed to offer any concrete evidence to the contrary, and instead wave aside Plaintiffs’ sworn testimony by mischaracterizing it in broad strokes as “hypothetical” or “imagined.” This dismissive approach is unpersuasive; Plaintiffs’ challenges are ripe; and the motion to dismiss should be denied.

2. On the merits, the Final Rule is invalid under the Administrative Procedure Act

because it exceeds the Department’s statutory authority, is not in accordance with law, and is arbitrary and capricious. Most notably, production of the administrative record following its court-ordered completion reveals that a central factual assertion the Department relied on to support this rulemaking—namely, the number of complaints of discrimination the agency has received in the past three years—is simply false: nearly 95% of the complaints of discrimination that the Department claims formed the basis for the Final Rule in fact *have nothing to do* with the federal refusal statutes. It is hard to find a clearer case of arbitrary agency action than when an agency falsely cites to evidence that it does not actually have to support its action.

Defendants argue that the rule clears APA review because Defendants “considered” the concerns identified in public comments, and that the rule “simply clarifies” the Department’s enforcement process. But mere consideration of public comments does not establish a reasoned basis for agency action where that consideration was window-dressing; and counsel’s assurances of regulatory modesty contrast starkly with the grand proclamations the federal government has spent two years delivering by Executive Order and in statements from senior officials—including the President and members of his cabinet—regarding the true intended scope and breadth of this rulemaking. The Final Rule should be vacated under the APA.

3. Plaintiffs are also entitled to relief on their constitutional claims. The Final Rule is a paradigmatic example of executive branch overreach that violates the Spending Clause proscription on gun-to-the-head coercion: it retroactively conditions hundreds of billions of dollars of critical federal health care funds on compliance with new and indeterminate policy pronouncements regarding how the federal health care refusal statutes should be broadened and redefined. And the rule violates the Establishment Clause because it impermissibly advances religious beliefs, effectively *requiring* Plaintiffs to hire employees who cannot deliver health

services critical to the entity’s mission, and thus to conform their business practices to the employee’s own religious practices.

Plaintiffs therefore respectfully request that the Court vacate and set aside the Final Rule.

ARGUMENT

I. Defendants’ motion to dismiss should be denied.

Defendants move to dismiss Plaintiffs’ Spending Clause and Establishment Clause claims for lack of subject-matter jurisdiction on the ground that Plaintiffs’ claims are unripe until Defendants take specific enforcement action under the Final Rule. Defs.’ Mem. 18-23. The motion should be denied because the Final Rule (1) requires Plaintiffs to adjust their conduct now, and (2) presents a risk of serious hardship to Plaintiffs absent adjudication of their claims.

A. Legal standard for assessing Defendants’ motion to dismiss.

A complaint need only set forth “a short and plain statement of the grounds for the court’s jurisdiction,” and “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a). Under Rule 12(b)(1), Plaintiffs bear the burden of demonstrating that the Court has subject-matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Plaintiffs may rely on the pleadings and any supporting affidavits, and the Court should “construe jurisdictional allegations liberally and take as true uncontroverted factual allegations.” *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994).

B. Plaintiffs’ constitutional challenges are ripe for judicial review.

1. Plaintiffs’ claims are ripe because the Final Rule requires Plaintiffs to adjust their conduct immediately.

Defendants assert that Plaintiffs’ constitutional claims are not yet ripe because “Plaintiffs have identified no specific enforcement action taken against them under the Rule.” Defs.’ Mem. 18. But this argument ignores both the explicit purpose and intended effect of the Final Rule,

which is to compel Plaintiffs’ and others’ *compliance* with Defendants’ unlawfully and unreasonably expanded interpretation of federal funding statutes. *See, e.g.*, 84 Fed. Reg. at 23,179 (“Department is . . . required to ensure . . . the compliance of its funding recipients.”); *id.* at 23,227-29 (the rule “incentivizes the desired behavior” by expanding enforcement in light of “[i]nadequate [existing] enforcement tools”); *id.* at 23,269-70 (requiring grantees to sign enforceable assurances and certifications of compliance). Defendants’ threatened enforcement is merely a means of ensuring that compliance, not the object of the Final Rule. And “agency action is ‘ripe’ for review at once” when “as a practical matter [it] requires the plaintiff to adjust his conduct immediately.” *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990).

Plaintiffs’ complaint alleges that once the Final Rule becomes effective, Plaintiffs will have no choice but to either acquiesce in the Final Rule’s unconstitutional conditions, or risk losing billions of funds that the Final Rule plainly authorizes HHS to terminate or withhold. *See Compl. ¶¶ 1-4, 80-88, 133-158; Pls.’ PI Mem. 10-14; see also infra* Parts III.B, IV.A. The immediate obligation to comply with the Final Rule—or risk losing billions in critical public health funds—is an immediate harm that this Court can and should address, and constitutes the very threat that the limitations on the spending power proscribe. *See Nat'l Fed'n of Indep. Business ("NFIB") v. Sebelius*, 567 U.S. 519, 580-81 (2012) (underscoring concerns with respect to the “nature of the threat” posed by the Medicaid provisions of the Affordable Care Act); *id.* at 581 (explaining that “[b]y financial inducement the Court meant the threat of losing . . . funds” (internal quotation marks omitted)). When Plaintiffs “ha[ve] no choice, the Federal Government can achieve its objectives without accountability,” *id.* at 578, and Plaintiffs’ well-pleaded allegations regarding the impact of HHS’s fund-termination authority establish a real and imminent claim of unconstitutional government action. *See Compl. ¶¶ 1-4, 80-88, 133-158.*

Defendants also assert that the “scope of funding that may be at risk is unknown,” Defs.’ Mem. 20, but the Final Rule authorizes HHS to withhold or terminate billions of dollars in federal funding for even suspected violations of the Final Rule and its underlying statutes—as Defendants never contest, and as Plaintiffs clearly pled. *See Compl.* ¶¶ 1-4, 80-88, 133-158. In fact, *all* of Plaintiffs’ federal health care funding is at risk, as Defendants elsewhere concede. Defs.’ Mem. 4 (“Plaintiffs . . . have the straightforward remedy of no longer accepting the conditioned federal funds.”). Plaintiffs are not required to gamble with that critical funding before this Court may adjudicate their constitutional claims. There is no risk of judicial entanglement in abstract disagreements here, *see Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967)); and this Court need not wait until an enforcement action is taken under the Final Rule to conclude that Plaintiffs’ claims are ripe for review, *see City of New York v. U.S. Dep’t of Commerce*, 739 F. Supp. 761, 766 (E.D.N.Y. 1990).¹ The Final Rule standing alone seeks to compel changes in Plaintiffs’ behavior or expose them to the risk of fund termination on the day it takes effect—with extremely disruptive consequences for Plaintiffs and the public health either way. Compl. ¶¶ 80-88, 133-158; Pls.’ PI Mem. 13-14.

In any event, even assuming that ripeness depended on HHS’s enforcement decisions, the likelihood of enforcement actions to terminate funds is sufficiently high to warrant adjudication of Plaintiffs’ constitutional claims. It is hardly “hypothetical[],” Defs.’ Mem. 20, that HHS plans to use the threat of funding termination to induce compliance with the Final Rule’s new

¹ The cases that Defendants cite with respect to the Weldon Amendment are either inapposite, or further support that Plaintiffs’ claims are ripe for review. As Defendants themselves explain, *Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Gonzalez*, 468 F.3d 826 (D.C. Cir. 2006), dismissed the plaintiff’s claims for lack of constitutional standing, which Defendants do not challenge in this case. In *California v. United States*, No. 05-cv-328, 2008 WL 744840 (N.D. Cal. Mar. 18, 2008), the Court made clear that when the federal government either determined that enforcing state law would violate the Weldon Amendment “or refuse[d] to provide an answer, thus leaving California in a difficult position of putting at risk billions of dollars in federal funds if it enforces its own statute, the case then would be ripe for a court to determine this matter.” *Id.* at *6. This is exactly the “unfortunate situation” Plaintiffs confront here. *Id.*

requirements; HHS has said so itself, explicitly stating that one purpose in issuing the Final Rule is to address its “[i]nadequate enforcement tools to address unlawful discrimination and coercion.” 84 Fed. Reg. at 23,228. Yet, there is no evidence at all in the administrative record that a single complaint of discrimination was unable to be remedied with the Department’s existing tools. *See infra* Part II.C.1. This lack of evidence can only suggest that HHS intends to wield its new powers under the Final Rule to induce Plaintiffs to accept its new conditions.

Plaintiffs’ Establishment Clause claim similarly presents “a concrete dispute between the parties.” *Sharkey v. Quarantillo*, 541 F.3d 75, 89 (2d Cir. 2008); *see also Nat’l Org. for Marriage*, 714 F.3d at 689 (courts “assess pre-enforcement First Amendment claims . . . under somewhat relaxed standing and ripeness rules”). This claim turns on a straightforward legal analysis of the Final Rule’s definition of “discrimination.” That definition, at subsection (4), provides that an employer “shall not be regarded as having engaged in discrimination” against an objecting employee where the employer offers, and the employee “voluntarily accepts an effective accommodation.” 84 Fed. Reg. at 23,263 (§ 88.2). Plaintiffs allege that this definition (as elaborated by the limited discussion in the rule’s preamble, *see id.* at 23,190-92) violates the Establishment Clause because it permits an employee an unqualified right to refuse work for religious reasons, and accordingly requires employers like Plaintiffs to conform their business practices to the objecting employee’s religious practices. *See* Compl. ¶¶ 73, 198-201. Although HHS disagrees on the merits that the Final Rule violates the Establishment Clause, *see* Defs.’ Mem. 67-70, nowhere does the agency assert that the application of this definition is too “abstract” for the Court’s review. *Abbott Labs.*, 387 U.S. at 148-49.

2. Plaintiffs face hardship absent the Court’s consideration.

In addition, delaying review of these claims would cause immense and immediate harm to Plaintiffs and the public interest. *See id.* at 152-54; *see also New York v. U.S. Dep’t of*

Commerce, 351 F. Supp. 3d 502, 626-27 (S.D.N.Y. 2019). Plaintiffs face hardship “where a regulation requires an immediate and significant change in the plaintiffs’ conduct of their affairs with serious penalties attached to noncompliance.” *Abbott Labs.*, 387 U.S. at 153; *see also* *Thomas v. City of New York*, 143 F.3d 31, 36 (2d Cir. 1998) (pre-enforcement challenge ripe where “plaintiffs must either incur great expense to comply with the requirements, or (if they choose to challenge the regulation through noncompliance) run the risk of incurring potentially even greater burdens”).

This is exactly the situation Plaintiffs face. Plaintiffs’ complaint alleges extensive, imminent, and potentially devastating injuries caused by the Final Rule. *See* Compl. ¶¶ 100-158. Plaintiffs’ motion for preliminary injunction and supporting evidence further establish that the Final Rule will cause—and already has begun causing—these imminent harms. *See* Pls.’ PI Mem. 10-22. Among these harms are significant administrative, policy, human resources, and other efforts Plaintiffs must undertake to come into compliance prior to the Final Rule’s effective date, *id.* at 11-13 & nn.11-14, including efforts that have already begun. *See, e.g.*, Ex. 29 (Lucchesi Decl.) ¶ 22; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 19-20; Ex. 46 (Wagaw Decl.) ¶ 18. Indeed, HHS expressly states that one purpose of the Final Rule is to “institute proactive measures” by grantees like the Plaintiffs. 84 Fed. Reg. at 23,228. And Plaintiffs face “serious penalties attached to noncompliance,” *Abbott Labs.*, 387 U.S. at 153, through the risk of losing billions of dollars in federal funds necessary to deliver health care to their residents. *See* Compl. ¶¶ 80-88, 133-158; Pls.’ PI Mem. 13-14.

The fact that Plaintiffs must make immediate changes to the conduct of their affairs is not surprising, given the upheaval the Final Rule causes to their direct delivery of health care. As Plaintiffs alleged in their complaint and documented in the motion for preliminary injunction,

their hospitals have policies on accommodating religious objection, many of which track state laws and Title VII. *See* Compl. ¶¶ 112-114; Pls.’ PI Mem. 15-16 & n.15. And as Plaintiffs also extensively documented, the Final Rule’s definition of “discrimination” departs from the framework underlying their policies by, *inter alia*, allowing an employee to determine whether she has been discriminated against by tying such determination to whether she voluntarily accepts an employer’s accommodation—a sea change that requires Plaintiffs’ policies to be rewritten, eliminates Plaintiffs’ ability to employ efficient and cost-conscious staffing arrangements, and imposes burdens on Plaintiffs’ non-objecting staff. *See* Compl. ¶¶ 73-74, 79, 119-132; Pls.’ PI Mem. 16-18 & nn.17-18.

Furthermore, changing their religious accommodation policies to permit objections in accordance with the Final Rule will require Plaintiffs to make staffing changes in emergency and rural settings, among others, and such changes threaten irreparable injury to the reputation of Plaintiffs’ health institutions. *See* Compl. ¶¶ 119-132; Pls.’ PI Mem. 18-22. Plaintiffs “deal in a sensitive industry, in which public confidence in their [services] is especially important,” and “[t]o require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily.” *Abbott Labs.*, 387 U.S. at 153; *cf. City of Chicago v. Sessions*, 264 F. Supp. 3d 933, 950 (N.D. Ill. 2017) (risk of reputational injury causes irreparable harm). Indeed, delaying judicial review until *after* Plaintiffs have been either forced to change their policies, stripped of billions of dollars in health care funds, or subjected to federal enforcement action “would result in extreme—possibly irremediable—hardship.” *Dep’t of Commerce v. U.S. House of Representatives*, 525 U.S. 316, 332 (1999).

Because Plaintiffs’ constitutional claims are ripe for judicial review, Plaintiffs

respectfully request that the Court deny Defendants' motion to dismiss.²

II. The Final Rule violates the Administrative Procedure Act.

Plaintiffs are entitled to summary judgment on their claims that the Final Rule violates the Administrative Procedure Act ("APA") because "there is no genuine dispute as to any material fact and [Plaintiffs are] entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

The APA provides that courts must "hold unlawful and set aside" agency action that is "in excess of statutory jurisdiction, authority, or limitations"; that is "not in accordance with law"; or that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. §§ 706(2)(A), (C). Defendants assert that under the APA, the Final Rule is "presumed valid." Defs.' Mem. 17, 52. There is no support for this assertion; to the contrary, Congress intended for courts to conduct rigorous judicial review of agency action under the APA in order to maintain the balance of power between the branches of government: "[I]t would be a disservice to our form of government and to the administrative process itself if the courts should fail, so far as the terms of the [APA] warrant, to give effect to its remedial purposes." *Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J., concurring) (in enacting the APA, "Congress confined agencies' discretion and subjected their decisions to judicial review").

Although it is correct that under the APA, "[a] reviewing court may not itself weigh the evidence or substitute its judgment for that of the agency," this standard does not support the claim of presumptive validity Defendants assert; instead, "within the prescribed narrow sphere,

² Defendants also argue in general terms that all of Plaintiffs' claims should be dismissed for failure to state a claim, Defs.' Mem. 16, but do not appear to present a distinct argument on Rule 12(b)(6) grounds apart from their arguments on the merits. Defs.' Mem. 23-73. Under Rule 12(b)(6), Plaintiffs "need only allege 'enough facts to state a claim to relief that is plausible on its face.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 n.12 (2011) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). For the reasons stated in Plaintiffs' opposition to Defendants' merits arguments in this memorandum, Plaintiffs easily clear the Rule 12(b)(6) threshold.

judicial inquiry must be searching and careful.” *Islander E. Pipeline Co., LLC v. McCarthy*, 525 F.3d 141, 150-51 (2d Cir. 2008) (quotation marks and citation omitted). The Supreme Court has long made clear that the APA requires this Court to conduct “plenary review of the Secretary’s decision,” *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), and that this review is to be “thorough, probing, [and] in-depth,” *id.* at 415.

Here, there is no dispute of material fact that the Final Rule exceeds the Department’s statutory authority, is not in accordance with law, and is arbitrary and capricious.

A. The Final Rule violates the APA because it exceeds the Department’s statutory authority.

The APA requires this Court to set aside agency action that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C. § 706(2)(C). For the reasons explained in the Provider Plaintiffs’ summary judgment memorandum and Plaintiffs’ preliminary injunction memorandum, the Final Rule exceeds the Department’s statutory authority and violates the APA. *See* Provider SJ Mem., Part I; *see also* Pls.’ PI Mem. 25-30.

B. The Final Rule violates the APA because it is not in accordance with law.

The APA provides that the Court shall “hold unlawful and set aside” agency action that is “not in accordance with law.” 5 U.S.C. § 706(2)(A). For the reasons explained in the Provider Plaintiffs’ summary judgment memorandum and Plaintiffs’ preliminary injunction memorandum, the Final Rule is not in accordance with law because it violates the ACA’s Non-Interference Mandate and impairs the federal statutory guarantee of access to emergency medical care. *See* Provider SJ Mem., Parts II.A, II.B, II.D; *see also* Pls.’ PI Mem. 30-36.

In addition, the Final Rule conflicts with the Medicaid informed consent requirements and violates the Paperwork Reduction Act, as set out below.

1. The Final Rule conflicts with the Medicaid informed consent requirements that apply to counseling and referral services.

The Final Rule conflicts with the Medicaid counseling and referral provision it purports to implement. *See* Pls.’ PI Mem. 32-33. That statute provides that Medicaid managed care organizations will not be required to provide counseling or referral services if the organization objects on moral or religious grounds. 42 U.S.C. § 1396u-2(b)(3)(B). Congress, however, expressly cabined these refusal rights by providing that with regard to informed consent, the counseling and referral provision shall not “be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.” *Id.* Because the Final Rule includes no exception for state-law disclosure requirements, 84 Fed. Reg. at 23,266-67 (§ 88.3(h)(1)(ii), (h)(2)(ii)), the Department’s implementation of this provision exceeds its authority.

Defendants argue that the Final Rule “does not implicate any state disclosure requirements except to the extent they rely on [§ 1396u-2(b)(3)(B)] for authority,” and that the Medicaid informed consent requirement “is simply not implicated here.” Defs.’ Mem. 49. But nothing in the Final Rule limits its reach in the way Defendants now propose; § 88.3(h)(1)(ii) provides that “[a]ny State agency that administers a Medicaid program is required to comply with,” *inter alia*, sub-paragraph (h)(2)(ii); and that sub-paragraph in turn includes a blanket restriction on requiring an objecting Medicaid managed care organization to provide counseling or referral services, with no exception for state disclosure laws. 84 Fed. Reg. at 23,266-67. A regulation may be upheld only “on the basis articulated by the agency itself”—not on “counsel’s post hoc rationalizations.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

2. The requirement that Plaintiffs submit written assurances and certifications of compliance is not in accordance with law.

Plaintiffs explained in their memorandum supporting a preliminary injunction that the assurance and certification requirements in the Final Rule, 84 Fed. Reg. at 23,269, are not in accordance with law because the Department failed to comply with the Paperwork Reduction Act (“PRA”). *See* Pls.’ PI Mem. 35-36. Defendants’ one-sentence response effectively concedes this point, arguing only that *after* the Final Rule was published, the Department belatedly sought to comply with its obligations and “fully expects approval prior to the Rule’s revised effective date.” Defs.’ Mem. 51.

Defendants’ response does not cure this legal infirmity. First, as of today, these data collection requirements still have not been approved; and Defendants cannot seriously be asking the Court to ignore a conceded APA violation because the Department “fully expects” that a non-party (the OMB Director) may take action in the future. *Cf. Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 179 (2d Cir. 2006) (agency decision was arbitrary where instead of complying with statutory requirement, “agency simply stated its intent to do better the next time”).

Second, the Information Collection Request that the Department belatedly submitted to OMB seeks approval only for the assurance requirement, not the certification of compliance. *See* Information Collection Request, *Request for OMB Review and Approval*, at 5 (June 19, 2019), at <https://www.reginfo.gov/public/do/DownloadDocument?objectID=92774800> (“Note that this information collection request does not include the related certification of compliance in section 88.4(b).”).³ Defendants’ incomplete attempt at post-hoc compliance with its legal obligations renders the assurance and certification requirements invalid under the APA.

³ *See also* Information Collection Request—Agency Submission, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201906-0945-003.

C. The Final Rule is arbitrary and capricious in violation of the APA.

Under the APA, the Court must “hold unlawful and set aside” agency action that is “arbitrary, capricious, [or] an abuse of discretion.” 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if the agency “entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [made a decision that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *State Farm*, 463 U.S. at 43. Furthermore, agency changes to longstanding policies that have engendered reliance interests over time must “show that there are good reasons for the new policy,” and provide a “detailed justification” for its new direction to survive arbitrary and capricious review. *Fox*, 556 U.S. at 515.

The Department’s stated reasons for implementing the Final Rule are unsupported and inconsistent with the record evidence; the Department failed entirely to consider the record evidence of significant upheaval the Final Rule would cause; and despite that record evidence, the Department grossly failed to appropriately assess the costs and benefits of its rulemaking.

1. HHS has justified the Final Rule on the basis of asserted problems that do not in fact exist.

HHS’s repeated refrain that the Final Rule is necessary to address confusion created by the 2011 Rule, and to adequately provide for enforcement of federal conscience protections, is unsupported by the record and therefore arbitrary and capricious. HHS fails to “acknowledge . . . record evidence directly contradicting its [stated rationales for the Final Rule],” *Islander E. Pipeline Co., LLC v. Conn. Dep’t of Envtl. Prot.*, 482 F.3d 79, 102 (2d Cir. 2006), and does not satisfactorily provide a “rational connection between the facts found and the choice made,” *State Farm*, 463 U.S. at 43 (internal quotation marks omitted).

First, HHS claims that the Final Rule is necessary to address confusion created by the

2011 Rule. *See* 84 Fed. Reg. at 23,175, 23,228. HHS claims that:

The 2011 Rule created confusion over what is and is not required under Federal conscience and anti-discrimination laws and narrowed OCR’s enforcement processes. Since November 2016, there has been a *significant increase* in complaints filed with OCR *alleging violations of the laws that were the subject of the 2011 Rule*, compared to the time period between the 2009 proposal to repeal the 2008 Rule and November 2016. The increase underscores the need for the Department to have the proper enforcement tools available to appropriately enforce all Federal conscience and anti-discrimination laws.

84 Fed. Reg. at 23,175 (emphasis added); *see also id.* at 23,229 (separately calculating the number of complaints, and stating that OCR received 34 complaints between November 2016 and January 2018, and 343 during fiscal year (“FY”) 2018); *id.* at 23,183 (“This rule provides appropriate enforcement mechanisms *in response to a significant increase* in complaints alleging violations of Federal conscience and anti-discrimination laws.”) (emphasis added)).

But on review of the administrative record, this rationale proves false. Prior to the November 2016 election, evidence of confusion with respect to the underlying statutes and the current regulatory scheme is slim to non-existent: as HHS itself highlights, the Department only received ten complaints alleging violations of federal conscience protections between 2009 and November 2016. *See* 83 Fed. Reg. at 3886. Subsequently, HHS purportedly received 34 complaints between November 2016 and January 2018, and 343 complaints in FY 2018 when it issued the notice of proposed rulemaking. *See* 84 Fed. Reg. at 23,229.⁴ However, the vast

⁴ HHS misleadingly suggests that the 34 complaints received between November 2016 (after the election) and January 2018 are distinct from the 343 complaints received in FY 2018. The relevant fiscal year, however, is from October 1, 2017 to September 30, 2018. *See* <https://www.usa.gov/budget>. Accordingly, some of the 34 complaints overlap with the 343 complaints. Given this confusion, Plaintiffs requested that Defendants’ counsel direct Plaintiffs to the bates numbers for the 34 complaints, but Defendants never provided that information. *See* Ex. 135 (Miller Decl.) ¶¶ 4-9.

From what Plaintiffs have been able to discern, the administrative record shows 358 unique complaint numbers for the period between the November 2016 election and the end of FY 2018 on the index provided by HHS. *See* Ex. 135 (Miller Decl.) ¶¶ 10-11 & Ex. 135-A. Twenty-two of those complaints are exact duplicates, *see* Ex. 135 (Miller Decl.) ¶ 12 & Ex. 135-B, leaving 336 unique complaints. Ex. 135 (Miller Decl.) ¶ 13. As Plaintiffs explain further, *infra*, the vast majority of these unique complaints are irrelevant to the underlying refusal statutes or the Final Rule.

majority of complaints received after November 2016 reflect a fundamental misunderstanding of what federal conscience laws require or protect.

Tellingly, Defendants now concede that “a large subset of” the complaints received by HHS after November 2016 “complain of conduct that is outside of the scope of the Federal Conscience Statutes and the [Final] Rule.” Defs.’ Mem. 53. And while the Final Rule expressly claims a “*significant increase*” in complaints alleging violations of “Federal conscience and anti-discrimination laws,” 84 Fed. Reg. at 23,175 (emphasis added), Defendants now acknowledge, as they must, that only “*some*” of the complaints “do implicate the relevant statutes.” Defs.’ Mem. 53 (emphasis added).

These are startling admissions, yet still manage to understate matters. In response to comments that the Final Rule was unnecessary because of the number of complaints HHS had received, HHS made a specific empirical claim that “OCR received 343 complaints alleging conscience violations” in FY 2018. 84 Fed. Reg. at 23,229. Yet a review of the administrative record reveals that the vast majority of these complaints—approximately 79%—do *not* in fact allege conscience violations, and instead relate to vaccinations, *see* Ex. 135 (Miller Decl.) ¶ 15 & Ex. 135-F, which the Department expressly admits is beyond the scope of the Final Rule. *See, e.g.*, 84 Fed. Reg. at 23,183. Numerous other complaints have nothing to do with the topics the Final Rule purports to clarify,⁵ and a few vehemently *oppose* issuance of the Final Rule.⁶

⁵ See e.g., Ex. 123, AR 542627-36 (complaint filed because federal agencies forced complainant to remove social media ads for “divine cure for cancer”); Ex. 124, AR 543082-90 (parent alleging discrimination against a health care entity because parent did not want newborn to have a newborn screening test); Ex. 125, AR 543879-82 (allegations of identity theft and health care fraud); Ex. 126, AR 544035-43 (complainant upset about needing to purchase coverage for unneeded prescriptions); Ex. 128, AR 544235-43 (allegations of HIPAA violations when an entity posted medical records online); Ex. 131, AR 544753-62 (employee complains of suspension for refusing to meet with board of directors regarding unspecified grievances); *see also* Ex. 135 (Miller Decl.) ¶ 16 & Ex. 135-D.

⁶ See Ex. 121, AR 542414-22 (explaining HHS’s actions are “an appalling, unethical abuse of ‘religious freedom’ to impose archaic religious ideals on citizens in order to deny them civil liberties and health care”); Ex. 122, AR

Indeed, of the total number of complaints in the record received by HHS since November 2016, a mere *six percent* (21 complaints) allege conduct that is even arguably covered by the refusal statutes or Rule. *See* Miller Decl. ¶ 17 & Exs. 135-F, 135-G.⁷

The mismatch between the agency’s stated explanation for the Final Rule and the actual facts in the administrative record cannot be overstated. HHS has woefully failed to substantiate its claim that “allegations and evidence of discrimination and coercion have existed since the 2008 Rule and increased over time.” 84 Fed. Reg. at 23,175. It comes nowhere near supporting its assertion that there has been a “significant increase” in complaints related to the refusal statutes. *Id.* The agency’s very specific claim of 343 complaints in FY 2018 that allege violations of these laws turns out to be patently false. “Suffice it to say, it is arbitrary and capricious for an agency to base its decision on a factual premise that the record plainly showed to be wrong.” *NRDC v. Rauch*, 244 F. Supp. 3d 66, 96 (D.D.C. 2017) (citing *State Farm*, 463 U.S. at 43); *cf. Dep’t of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019) (invalidating agency action where “the evidence tells a story that does not match the explanation the Secretary gave for his decision”). That is exactly the case here, as Defendants now all but admit.⁸ Far from supporting HHS’s contention that the 2011 Rule needed clarification, the record shows that if anything, the Department’s proposal to significantly alter the status quo has sown more confusion in the past year than in the previous seven years combined.

542449-57 (“The Current Administration has allowed religious Zealots to run health information agencies.”).

⁷ Plaintiffs do not concede that all of these complaints are legitimate. And while Plaintiffs do not always agree with HHS’s interpretation of the scope of the refusal statutes, *see, e.g.*, 84 Fed. Reg. at 23,178-79 (discussing Weldon Amendment), for purposes of this brief Plaintiffs have erred on the side of including such complaints in this category.

⁸ Defendants contend that the supposed increase in complaints was just one of “many metrics” the agency relied on, Defs.’ Mem. 53, but Defendants have not here illuminated what those other metrics are, and they do not disagree that complaint volume was in fact a central reason the agency gave for promulgating the Final Rule. A rulemaking that relies a mischaracterization of the actual record evidence is arbitrary. *City of Phila. v. Sessions*, 280 F. Supp. 3d 579, 623-24 (E.D. Pa. 2017).

HHS's second justification for the Final Rule—" [i]nadequate enforcement tools to address unlawful discrimination and coercion," 84 Fed. Reg. at 23,228—also finds no support in the administrative record, and is again counter to the evidence. As explained above, the majority of complaints upon which HHS relies to promulgate the Final Rule do not require enforcement by the Department, or even fall within the scope of the Final Rule or the underlying statutes, as HHS concedes. Moreover, with respect to most of the complaints in the record, there is zero evidence that HHS investigated them at all, or needed more authority to do so.⁹ The record further reveals that in the small number of instances where HHS investigated complaints, they were largely unfounded or otherwise satisfactorily resolved.¹⁰ Indeed, HHS highlights the corrective actions health care providers and institutions took in response to OCR investigations. *See, e.g.*, 83 Fed. Reg. at 3,886 (explaining that after OCR conducted investigations of complaints, relevant entities revised policies, posted notices, trained personnel about statutory obligations, and made public announcements indicating changes to practices). Where, as here, the record evidence "directly contradicts the unsupported reasoning of the agency and the agency fails to support its pronouncements with data or evidence," courts will not defer to agency action. *Islander*, 482 F.3d at 103.

Effectively conceding that the Department's reliance on a supposed record of hundreds of conscience complaints is false, Defendants now point to only three complaints in the entire

⁹ There is no evidence in the administrative record pertaining to any investigation of the FY 2018 complaints, with the exception of one complaint. *See* Ex. 135 (Miller Decl.) ¶ 18 & Ex. 135-E. And with respect to complaints filed before November 2016, HHS concedes that nearly all have been resolved. *See* 83 Fed. Reg. at 3886. Further, HHS offers no explanation for why two pre-November 2016 complaints remain open, but in any event there is nothing on the face of these complaints to suggest it is because the Department lacks enforcement authority. *See* Ex. 132, AR 545712-16 (Aug. 15, 2014 complaint alleging complainant denied admission privileges because she performed abortions); Ex. 133, AR 545736-40 (Nov. 4, 2015 complaint alleging California's FACT Act violates federal law).

¹⁰ *See, e.g.*, Ex. 120, AR 541967 (OCR closed matter because complaint failed to state a claim of discrimination); Ex. 119, AR 541805 (complaint withdrawn when grantee took actions to come into compliance); *see also* Ex. 135 (Miller Decl.) ¶ 18 & Ex. 135-E (listing record evidence of 14 resolved complaints).

administrative record that purportedly “implicate the relevant statutes.” Defs.’ Mem. 53. Even this thin showing undermines, rather than supports, the Department’s stated reasons for the Final Rule. As noted below, two of the complaints concern issues or entities that are not subject to the underlying statutes; and as to all three, there is nothing in the administrative record to suggest these complaints were even investigated, let alone that they could plausibly form a basis for concluding that the Department needed greater enforcement authority.

Specifically, the first complaint Defendants cite is a 2018 letter from the American Association of Pro-Life Obstetricians and Gynecologists (“AAPLOG”) to OCR complaining about a decade-old ethics committee opinion by the American College of Obstetricians and Gynecologists (“ACOG”) that, according to AAPLOG, leaves ob-gyns “vulnerable to the possibility that his or her conscience-based refusal to participate in abortion could be considered unethical.” Ex. 129, AR 544525. The letter fails to refer to a single example of this “discrimination” occurring in the more than ten years since the ethics committee opinion was published.¹¹ But even if it had, ACOG is a professional organization of doctors and is plainly not subject to any of the refusal statutes. It makes no sense, then, to point to this complaint as evidence of confusion over the scope of the refusal statutes, or of the inadequacy of existing enforcement mechanisms.

The second complaint Defendants cite provides even less support for HHS’s stated rationales for the Final Rule. Ex. 127, AR 544188. This 2018 complaint, by an employee of the Washington State Department of Corrections, alleges discrimination based on a refusal to provide hormone therapy to incarcerated transgender persons. Because the objected-to conduct

¹¹ Moreover, the administrative record includes a statement by ACOG explaining that the committee opinion will *not* be used to determine whether an ob-gyn was entitled to board certification. Ex. 129, AR 544516, at 544557-58; *see also id.* at AR 544555 (letter from American Board of Obstetrics & Gynecology to then-Secretary of HHS Michael O. Leavitt).

has nothing to do with abortion or sterilization procedures, the complaint, by definition, does not implicate the Church (b), (c)(1), (e), Coats-Snowe, or Weldon Amendments. The only refusal statute provisions that could even arguably be at issue here are Church (c)(2) or Church (d). Church (c)(2), however, concerns the rights of employees of entities that receive biomedical and behavioral research funds administered by HHS. *See* 42 U.S.C. § 300a-7(c)(2). However, federal law severely restricts HHS-funding of biomedical or behavioral research on incarcerated persons, subject to discrete and narrow exceptions. *See* 45 C.F.R. § 46.306(a)(2). Meanwhile, Church (d) only applies to a “health service program or research activity funded in whole or in part under a program administered by” HHS, 42 U.S.C. § 300a-7(d), and therefore, “does not encompass . . . medical treatments and services performed by health care providers [that] are not ‘part of’ a health service program receiving funding from HHS,” 84 Fed. Reg. at 23,197. Defendants do not identify any HHS-funded program that provides gender-affirming health care to individuals incarcerated in state prisons and, as such, fail to explain how this complaint implicates any of the federal refusal statutes.¹²

This leaves a single complaint identified in HHS’s brief that even arguably states a violation of the refusal statutes. *See* Ex. 130, AR 544612. That is far too thin a reed to rationally support the agency’s express justification for the Final Rule: a “*significant increase* in complaints filed with OCR *alleging violations of the laws that were the subject of the 2011 Rule*,” 84 Fed. Reg. at 23,175. Nor does the face of this complaint lend any support to HHS’s second justification that it has inadequate enforcement tools at its disposal to address the issues it presents. 84 Fed. Reg. at 23,228. Indeed, the administrative record contains nothing with

¹² For example, federal law prohibits states from using federal Medicaid matching funds for health care services provided to adult and juvenile inmates of public institutions, except when the inmate is admitted to an off-site hospital or other qualifying facility for at least 24 hours. 42 U.S.C. § 1393d(a)(29)(A).

respect to HHS's assessment of the complaint, or any investigation thereof.

Defendants' own attempt to identify evidence to support HHS's stated reasons for the Final Rule reveals that HHS's decision is "unsupported by substantial evidence," and therefore arbitrary and capricious. *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

2. The Department failed to provide a reasoned explanation for its policy change.

In addition, to survive arbitrary and capricious review, an agency must provide a substantial justification when "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015) (internal quotation marks omitted). The Final Rule implicates both concerns: the new policy rests on new factual findings based on substantially the same evidence the Department already considered in 2011 to reach the opposite conclusions; and Plaintiffs have relied on the prior policy as codified in the 2011 Rule, including the Department's previous view that existing "statutes strike a careful balance between the rights of patients to access needed health care, and the conscience rights of health care providers." 76 Fed. Reg. 9968, 9973 (Feb. 23, 2011).

In support of the Final Rule, the Department heavily relies on the same evidence that the agency considered in promulgating the 2011 Rule, which largely rescinded the 2008 Rule that had included many of the same onerous provisions found in the 2019 Final Rule.¹³ *See, e.g.*, Pls.' PI Mem. 4-9. Yet in 2011, after considering this information, HHS found that (1) "the 2008 final rule attempting to clarify the Federal health care provider conscience statutes ha[d] instead led to greater confusion," 76 Fed. Reg. at 9969; (2) "the 2008 Final Rule may negatively affect

¹³ This evidence includes a 2009 survey, 2009 journal article, news reports in 2010, and comments the Department received in response to the proposed rescission of the 2008 Rule. *See, e.g.*, 84 Fed. Reg. at 23,175-76.

the ability of patients to access care if interpreted broadly,” *id.* at 9974; and (3) the certification requirements imposed by the 2008 Rule “created unnecessary additional financial and administrative burdens on health care entities,” *id.* The Department’s reliance on the same evidence more than eight years later to reach precisely the opposite conclusions—with no explanation of why the Department’s assessment of those facts in 2011 was incorrect—is arbitrary and capricious. *See Organized Vill. of Kake v. U.S. Dep’t of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc) (holding an agency’s decision arbitrary and capricious when “it made factual findings directly contrary to” its previous policy following a change in presidential administrations, and “expressly relied on those findings to justify the policy change”); *see also Fox*, 556 U.S. at 515-16; *Islander*, 482 F.3d at 103.

The Department claims that it did “acknowledge that it was changing its policy,” Defs.’ Mem. 52, but far more than an “acknowledgement” was required by the APA. The Department was required to provide “a reasoned explanation” for its dramatic change in course, which it failed to do. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Instead, in responding to the many comments explaining that the Final Rule would jeopardize patient access to care¹⁴—one of the key findings underlying the 2011 Rule—the Department concluded “that finalizing the rule is appropriate *without regard to whether data exists . . .* about its effect on access to services.” 84 Fed. Reg. at 23,182. But “[a]n agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore

¹⁴ See, e.g., Ex. 87, AR 137920 (Comment, Attorneys General of New York, et al.) (“New York Comment”); Ex. 89, AR 138102 (Comment, Nat’l Family Planning & Reprod. Health Ass’n) (“NFPRHA Comment”); Ex. 99, AR 140484 (Comment, New York City Comm’n on Human Rights, et al.) (“NYC Comment”); Ex. 100, AR 147746 (Comment, Am. Civil Liberties Union) (“ACLU Comment”); Ex. 110, AR 149141 (Comment, Nat’l Women’s Law Ctr.) (“NWLC Comment”); Ex. 113, AR 160751 (Comment, Planned Parenthood Fed. of Am.) (“PPFA Comment”); Ex. 117, AR 161476 (Comment, Lambda Legal) (“Lambda Comment”).

inconvenient facts when it writes on a blank slate.” *Fox*, 556 U.S. at 537 (Kennedy, J., concurring).

The Department’s lack of reasoned explanation is particularly egregious given that the Final Rule’s radical departure from long-established policy will upend strong reliance interests. Plaintiffs and many others have developed staffing patterns and scheduling practices, hired personnel, entered into collective bargaining agreements, signed contracts with subrecipients, and otherwise structured their operations around HHS’s longstanding interpretation of the refusal statutes.¹⁵ HHS acted arbitrarily in disregarding these strong reliance interests of Plaintiffs, their health care institutions, and the populations they serve. *See Encino Motorcars*, 136 S. Ct. at 2126; *see also Chamber of Commerce v. U.S. Dep’t of Labor*, 885 F.3d 360, 387 (5th Cir. 2018) (vacating agency rule as arbitrary where it “transform[ed]” the “market . . . and . . . regulate[d] in a new way the thousands of people and organizations working in that market”).

3. In promulgating the Final Rule, the Department entirely failed to consider important aspects of the problem.

The APA requires this Court to set aside Defendants’ decision as arbitrary if Defendants “entirely failed to consider an important aspect of the problem.” *State Farm*, 463 U.S. at 43.

a. HHS failed to consider the Final Rule’s radical disruption of health care delivery.

A failure to address serious harms presented to the agency—with widespread impact on a regulated industry—constitutes arbitrary decisionmaking. *See, e.g., SecurityPoint Holdings, Inc. v. Transp. Sec. Admin.*, 769 F.3d 1184, 1188 (D.C. Cir. 2014) (vacating agency order where

¹⁵ See, e.g., Ex. 72, AR 67173 (Comment, Wash. Dep’t of Health) (“WA DOH Comment”); Ex. 76, AR 71138 (Comment, Ass’n of Am. Med. Colls.) (“AAMC Comment”); Ex. 86, AR 137905 (Comment, Calif. Dep’t of Justice); Ex. 87, AR 137920 (New York Comment); Ex. 89, AR 138102 (NFPRA Comment); Ex. 96, AR 140265 (Comment, BlueCross BlueShield Ass’n) (“BCBS Comment”); Ex. 97, AR 140350 (Comment, Calif. Dep’t of Insurance) (“CA Insur. Comment”); Ex. 99, AR 140484 (NYC Comment); Ex. 100, AR 147746 (ACLU Comment); Ex. 101, AR 147824 (Comment, Greater New York Hospital Ass’n) (“GNYHA Comment”); Ex. 113, AR 160751 (PPFA Comment).

agency failed even to consider potential harms of its changes to an airport advertising program); *Stewart v. Azar*, 313 F. Supp. 3d 237, 263 (D.D.C. 2018) (vacating HHS Secretary’s waiver of several requirements of expanded Medicaid because “[f]or starters, the Secretary never once mentions the estimated 95,000 people who would lose coverage, which gives the Court little reason to think that he seriously grappled with the bottom-line impact on healthcare.”). Courts also consider agency action arbitrary and capricious when the agency “fail[s] to address the commenters’ concerns.” *Ass’n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012).

Here, as discussed in the Provider Plaintiffs’ summary judgment memorandum and Plaintiffs’ preliminary injunction memorandum, the Final Rule defines key statutory terms in a manner that dramatically expands the scope and applicability of the underlying federal statutes and that will have a widespread impact on the health care industry. *See* Provider SJ Mem., Part II.A; *see also* Pls.’ PI Mem. 25-30, 37-38. The new definitions of “assist in the performance,” “referral,” and “discrimination” drastically expand the universe of individuals, entities, and conduct regulated by the refusal statutes, and radically disrupt Plaintiffs’ and other providers’ basic operations and ability to deliver care—including emergency care. Taken together, these definitions create a dangerous double bind for providers: “assist in the performance” and “referral” increase the number of prospective objectors from clinical staff to a potentially limitless group of workers, while “discrimination” prescribes unworkable limits on a provider’s ability to learn about possible objections among this expanded group of workers, thereby limiting providers’ ability to provide undisrupted patient care.¹⁶

¹⁶ Pursuant to the Final Rule, an employee (1) may not be asked, pre-hire, whether she can execute core functions of her job without objection; (2) has no affirmative duty to disclose an objection to any aspect of her work; (3) may object at any time to any task, without advance notice to her employer and regardless of the effect on patient health;

The administrative record contains evidence that the Final Rule would do serious damage to Plaintiffs and other providers around the country in just this way. Major industry organizations and health provider systems, representing or employing millions of health care workers, raised the following operational concerns to HHS:

- Expanding the universe of potential objectors beyond clinicians to other workers, *e.g.*, janitorial, scheduling, or other administrative staff, “could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances.” Ex. 91, AR 139590 (Comment, Am. Med. Ass’n) (“AMA Comment”); *see also* Ex. 72, AR 67174 (WA DOH Comment); Ex. 111, AR 151667 (Comment, California Med. Ass’n) (“CMA Comment”).
- An employee’s affirmative disclosure of an objection with meaningful advance notice to the employer is essential to the operations of hospitals and health providers, and its absence or restriction would disrupt business operations and jeopardize patient care. *See* Ex. 73, AR 67415 (Comment, Am. Hosp. Ass’n) (“AHA Comment”); Ex. 81, AR 134793 (Comment, San Francisco Dep’t of Pub. Health) (“SFDPH Comment”); Ex. 84, AR 137611 (Comment, Ohio Hosp. Ass’n); Ex. 92, AR 139641-42 (Comment, Kaiser Permanente) (“Kaiser Comment”); Ex. 101, AR 147825-26 (GNYHA Comment); Ex. 102, AR 147872 (Comment, Massachusetts Health & Hosp. Ass’n);
- Confusion as to how an objecting employee’s exercise of her right to refuse, pursuant to the expanded definitions of “assist in the performance” and “discrimination,” affects existing collective bargaining agreements governing employees, and whether a health provider could legally administer the rule’s requirements. *See* Ex. 81, AR 134793 (SFDPH Comment) (noting “problems with the fair administration of labor contracts between employees asserting conscience rights and those who do not”); Ex. 92, AR 139649 (Kaiser Comment); and
- The double bind of the definitions is especially destructive to “emergency departments, ambulance corps . . . and other urgent care settings” with extremely limited staffing, which cannot successfully plan for employee objections, consistent with the rule. Ex. 99, AR 140486 (NYC Comment) (noting the “very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems”); *see also* Ex. 106, AR 147982 (Comment, Am. Coll. of Emergency Physicians) (“ACEP Comment”) (observing the rule requires “an impossible task that jeopardizes the ability to provide care, both for standard

and (4) should an employer seek to accommodate an expressed objection, the employee has the categorical right to reject the accommodation as not “effective,” with no consequence to her employment. *See* 84 Fed. Reg. at 23,263 (definition of “discrimination”).

emergency room readiness and for emergency preparedness”).

Despite this extensive evidence in the administrative record, the Department entirely failed to consider disruptions to the operations of health providers, including Plaintiffs. None is mentioned or discussed in the Final Rule. Contrary to the Department’s argument, Defs.’ Mem. 55, these examples are not “hypothetical”—they are documented disruptions presented directly to the agency through the administrative record by major health systems and industry organizations, concerning the drastic effect the Final Rule will have on the delivery of health care by their institutions and members.¹⁷ The Department’s failure to consider these consequences is arbitrary. *See Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agencies must “adequately analyze . . . the consequences” of their actions); *see also SecurityPoint Holdings*, 769 F.3d at 1188; *Stewart*, 313 F. Supp. 3d at 263.

Second, HHS claims that it satisfied its obligations under the APA because it “modified each definition in response to the comments it received.” Defs.’ Mem. 56. But those modifications utterly failed to address the concerns raised.¹⁸ *See, e.g., Duncan*, 681 F.3d at 449. This is true as to each definition, and the change to “discrimination” is illustrative. In finalizing the rule, HHS added subsections (4)-(6) to the definition as proposed, purportedly to address commenters’ concerns about the Rule’s interaction with Title VII. *See* 84 Fed. Reg. at 23,190-92, 23,263. Yet nowhere does the agency address concerns that advance notice of an objection is essential to provider operations and patient care. And HHS does not dispute that, consistent with the Final Rule’s definition of “discrimination” (even as modified), an employee may object at

¹⁷ Though HHS describes Plaintiffs’ examples as “extreme,” it appears to endorse just such an extreme scope with respect to the definition of “assist in the performance.” Without in any way addressing the definition’s operational consequences or burdens on providers, HHS appears to agree that, *e.g.*, an employee who schedules an abortion would assist in the performance of that procedure. *See* 84 Fed. Reg. at 23,186-87.

¹⁸ Indeed, on this score HHS itself concedes that its modification of the definition of “referral” from the 2018 Proposed Rule to the 2019 Final Rule is “relatively minor.” 84 Fed. Reg. at 23,199.

any time to performing even core job functions—without advance notice and irrespective of patient harm—with no consequence to her employment. Nor does HHS anywhere address the “double bind” or cumulative effect of its definitions upon health providers, though this was set out squarely before the agency. *See, e.g., WildEarth Guardians v. Salazar*, 741 F. Supp. 2d 89, 102-03 (D.D.C. 2010) (agency action is arbitrary where the agency failed to consider “cumulative effect” of factors individually considered). The Final Rule is arbitrary and capricious because of the Department’s failure to consider the severe operational harms to providers that are extensively documented in the administrative record.

b. HHS failed to consider harms to public health and specific patient populations.

The Final Rule is arbitrary for the additional reason that the Department failed to consider, or to conduct a reasoned analysis regarding, the Final Rule’s impact on reducing access to care for large numbers of people—*e.g.*, women, LGBTQ people, immigrants and refugees, people living with HIV/AIDS or disabilities—who already face barriers to access. HHS “does not dispute that people in such demographic categories face health care disparities of various forms,” 84 Fed. Reg. at 23,251, and indeed such disparities and the harmful impacts of the Final Rule are documented in the administrative record through comments citing statistics, data, first-hand accounts from medical providers, and other evidence.¹⁹

Nor does the Final Rule account for the financial, physical, and mental harms—among other serious and wide-ranging negative effects—that patients who are denied care will suffer.

¹⁹ See, *e.g.*, Ex. 80, AR 134731-738 (Comment, Nat'l Ctr. for Lesbian Rights); Ex. 83, AR 135825-32 (Comment, Callen-Lorde Cnty. Health Ctr.); Ex. 108, AR 148073-74 (Comment, N.Y. State LGBT Health & Hum. Servs. Network); Ex. 109, AR 148096-107 (Comment, Nat'l Ctr. for Transgender Equality); Ex. 110, AR 149142-43, 149150-53 (NWLC Comment); Ex. 112, AR 160566-69 (Comment, GLMA: Health Professionals Advancing LGBT Equality) (“GLMA Comment”); Ex. 113, AR 160752-54 (PPFA Comment); Ex. 117, AR 161485-92 (Lambda Comment).

See, e.g., Provider Pls.’ PI Mem. at 18-19. These harms include adverse health outcomes for patients who are denied information about or access to care; increased costs and burden related to the need to obtain care from other sources; and the harms of forgone medical assistance when patients fear refusal by a provider.²⁰ The failure to account for these documented harms is arbitrary. *See Humane Soc’y of U.S. v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017); *see also Stewart*, 313 F. Supp. 3d at 263.

In the face of this evidence, HHS makes three arguments. First, the agency argues that commenters failed to identify suitable data allowing for reliable quantification of the Final Rule’s effects, Defs. Mem. 57-58, ignoring that it is the *Department’s* burden to establish a “rational connection between the facts found and the choice made.”²¹ *Nat’l Treasury Emps. Union v. Horner*, 854 F.2d 490, 498 (D.C. Cir. 1988) (internal quotation marks omitted).

Second, HHS discounts the record evidence on this point as “anecdotal accounts . . . unfit for extrapolation,” Defs. Mem 58, but this explanation is fatally inconsistent. The agency itself cites to anecdotal evidence in support of its belief that the Final Rule will increase the number of available providers, *see, e.g.*, 84 Fed. Reg. at 23,247, 23,252; and “[o]f course it would be arbitrary and capricious for the agency’s decision making to be ‘internally inconsistent.’” *NRDC v. U.S. Nuclear Regulatory Comm’n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018). HHS also discounts the record support of harms to patients because the Department did not consider it “empirical

²⁰ *See, e.g.*, Ex. 72, AR 67173 (WA DOH Comment); Ex. 73, AR 67413 (AHA Comment); Ex. 76, AR 71138 (AAMC Comment); Ex. 87, AR 137920 (New York Comment); Ex. 91, AR 139587 (AMA Comment); Ex. 94, AR 139749 (Comment, Am. Coll. of Obstetricians & Gynecologists) (“ACOG Comment”); Ex. 97, AR 140350 (CA Insur. Comment); Ex. 98, AR 140460 (Comment, Am. Acad. of Pediatrics); Ex. 99, AR 140484 (NYC Comment); Ex. 100, AR 147746 (ACLU Comment); Ex. 106, AR 147981 (ACEP Comment); Ex. 107, AR 148056 (Comment, Nat’l Immigration Law Ctr.); Ex. 110, AR 149141 (NWLC Comment); Ex. 113, AR 160751 (PPFA Comment); Ex. 116, AR 161178 (Comment, Inst. for Policy Integrity) (“IPI Comment”).

²¹ *See also infra* Part II.C.4 (concerning HHS’s cost-benefit analysis); Provider PI Mem. 17-18.

evidence,” 84 Fed. Reg. at 23,251; but here too, the Department has chosen to selectively credit non-empirical evidence that happens to support the Final Rule, including a summary of an outdated 2009 poll based on predictions about the effects of an entirely different rule (the 2011 Rule).²² *See* Defs.’ Mem. 54 (“There was nothing unreasonable, arbitrary, or capricious in HHS considering the poll among other non-empirical evidence.”). Selective reliance on non-empirical evidence only when supportive—combined with the refusal to consider like evidence when it undermines the agency’s position—is arbitrary. *See Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 69 (D.D.C. 2016) (reversing agency decision that “cherry-pick[ed] evidence”).

Third, HHS argues that the majority of comments on this topic “focused on *preexisting* discrimination in health care and did not attempt to answer the question of how the Rule itself would affect access to health care.” Defs.’ Mem. 58. As an initial matter, evidence of preexisting discrimination in health care is self-evidently germane to the agency’s consideration of how a new health care policy will affect already-vulnerable populations. *Cf. Friends of Back Bay v. U.S. Army Corps. of Eng’rs*, 681 F.3d 581, 588 (4th Cir. 2012) (“A material misapprehension of the baseline conditions existing in advance of an agency action can lay the groundwork for an arbitrary and capricious decision.”). In addition, among the handful of arguably pertinent complaints HHS cites to justify the specific need for the Final Rule, *see supra* Part II.C.1, is an objection that mirrors the very record evidence HHS discounts concerning the rule’s impact on access to care. To the extent that HHS believes a complaint from a correctional employee—who objected to providing hormone therapy to a transgender inmate—warrants new

²² Intervenors’ argument that Plaintiffs “do not challenge the survey’s methodology or results,” CMDA Mem. 24, is curious given that the record includes no information regarding the poll’s methodology. All that exists in the record is a two-page summary of the poll, Ex. 118, AR 537609-10; which makes HHS’s reliance on it as part of its justification for the Final Rule all the more arbitrary.

HHS enforcement powers under the Final Rule, the underlying facts are similar to the record evidence before the agency concerning barriers to access for transgender patients and heightened discrimination since HHS first proposed the rule.²³ The agency’s arguments about the evidence before them reflects either a complete failure to address these population-based patient harms or, at the least, the absence of a “reasoned analysis” and “satisfactory explanation of its action.”²⁴ *State Farm*, 463 U.S. at 42-43; *see also Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) (“[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions”) (emphasis in original).

c. HHS failed to consider the Final Rule’s interference with EMTALA.

The Final Rule is arbitrary and capricious because HHS failed to consider an important aspect of the problem that health care providers and entities repeatedly raised in response to the notice of proposed rulemaking—namely, how to reconcile the Final Rule with the Emergency Medical Treatment and Labor Act (“EMTALA”).

Commenters stressed that it was critical for HHS to confirm that the Final Rule would not affect EMTALA’s requirement that covered hospitals treat and care for patients in emergency situations.²⁵ As noted in the Provider Plaintiffs’ summary judgment memorandum, the Final

²³ See, e.g., Ex. 112, AR 160568 (GLMA Comment) (“Since the Department issued the proposed regulation, GLMA members have shared with us the ways they have seen religious objections used to the detriment of the healthcare of LGBT patients,” citing multiple accounts of barriers to access); Ex. 117, AR 161490-91 (Lambda Comment) (citing instance of clinic doctor refusing to provide hormone replacement therapy to a transgender woman, based on a religious objection).

²⁴ This defense also fails because it is inconsistent with the Department’s own reasoning in support of the Final Rule—in particular, HHS’s reliance on the “preexisting” CMDA poll, which did not attempt to answer the question of how *this* Rule would affect access to care, or even whether the 2011 rescission of the 2008 rule actually led to the exodus of health care providers that the 2009 poll predicted.

²⁵ See, e.g., Ex. 87, AR 137926-928 (New York Comment); Ex. 90, AR 139288 (Comment, Boston Med. Ctr.); Ex. 103, AR 147892 (Comment, Anne Arundel Med. Ctr.); Ex. 104, AR 147954 (The Disability Coalition); Ex. 113, AR 160755 (PPFA Comment); Ex. 114, AR 160821-22 (Comment, Ctr. for Reprod. Rights); Ex. 115, AR 161036-037 (Comment, Medicare Rights Ctr.).

Rule completely fails to address these significant and potentially life-threatening concerns. *See* Provider SJ Mem., Part II.B; *see also* Pls.’ PI Mem. 33-34.

The Final Rule’s four-sentence response to comments regarding EMTALA contains only curt and unreasoned factual statements (*e.g.*, “[t]his final rule . . . does not go into detail as to how its provisions may or may not interact with other statutes”), and generalities (*e.g.*, “[t]he Department intends to give all laws their fullest possible effect”), 84 Fed. Reg. at 23,183, that are insufficient to meet the APA’s requirement of reasoned decisionmaking. *See Citizens for Responsibility & Ethics in Washington v. FEC*, 316 F. Supp. 3d 349, 411 n.48 (D.D.C. 2018). HHS fails to provide any non-conclusory explanation of its unsupported conclusion that EMTALA’s requirement “does not conflict with Federal conscience and antidiscrimination laws.” 84 Fed. Reg. at 23,183. Instead, the Department merely references the reasoning in the preamble of the 2008 Rule. *See id.* By “relying only on generalized conclusions,” the Department’s assessment is arbitrary and capricious. *AEP Tex. N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010).

d. HHS failed to consider the Final Rule’s contravention of basic medical ethics.

HHS’s adoption of the definitions discussed above is also arbitrary and capricious because the agency failed to consider, or at minimum failed to conduct a reasoned analysis of, how those definitions violate basic ethical canons of the health professions. *See, e.g., Am. Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 399-400 (D.D.C. 1983) (invalidating HHS regulation on arbitrary-and-capricious grounds where the administrative record showed no attempt to balance “the malpractice and disciplinary risks that may be imposed upon physicians and hospitals caught between the requirements of the regulation and established legal and ethical guidelines”). In particular, the definition of “discrimination” permits an employee to object

without notice—irrespective of her duty of care or the needs of a patient—and the definitions of “assist in the performance” and “referral” violate the fundamental concept of informed consent by permitting health care entities and providers to withhold basic information from patients—even in emergencies. *See* 84 Fed. Reg. at 23,263-64 (definitions).

The administrative record contains evidence from organizations tasked with developing codes of ethics within the health professions, *e.g.*, the American Medical Association (“AMA”), American Nurses Association, and the Association of American Medical Colleges. These groups and others unequivocally informed HHS that:

- Current codes and professional standards allow individuals to refuse to provide services to which they object, but such objections are not unlimited and “must be balanced against the fundamental obligations of the medical profession”—*i.e.*, the needs of the patient; *see* Ex. 91, AR 139588 (AMA Comment);²⁶
- Physicians have a duty to provide medically indicated care in an emergency, irrespective of their moral or religious beliefs, and may not abandon a patient, *see id.*²⁷ and
- Physicians and other health professionals have a duty to inform patients about all relevant options for treatment, including options to which they object, *see id.*²⁸

Despite notice from organizations that have codified the ethical standards of the health professions—in the case of the AMA, for over a century—HHS failed to consider how its

²⁶ *See also* Ex. 70, AR 56915, at 56918 (Comment, Am. Nurses Ass’n) (“ANA Comment”) (nurse’s first duty is to the patient, citing Association’s code of ethics and World Medical Association standards); Ex. 101, AR 147824-25 (GNYHA Comment) (principle that objections must not compromise “standards of professional care and the rights of patients” reflects “broad consensus in health care professions and health care ethics”); Ex. 106, AR 147981, at 147983 (ACEP Comment) (noting “one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them”).

²⁷ *See also* Ex. 94, AR 139749, at 139750 (ACOG Comment) (“In an emergency in which referral is not possible or might negatively impact the patient’s physical or mental health, providers have an obligation to provide medically indicated and requested care The Proposed Rule disregards these rigorous standards of care established by the medical community.”); Ex. 105, AR 147963 (Comment, Ass’n of Women’s Health, Obstetric and Neonatal Nurses) (discussing abandonment).

²⁸ *See also* Ex. 76, AR 71138, at 71141-42 (AAMC Comment) (noting rule’s definition of “referral” is “incongruous with the standards of medical professionalism that are the core of a physician’s education and the practice of medicine”).

definitions contravene basic medical ethics. As a general matter, substantive references to “ethics” within the Final Rule overwhelmingly relate not to the patient, nor to what a health professional owes as a duty to that patient, but rather to the situation of the objector refusing to providing health care services—which the agency failed to “balance[] against the fundamental obligations of the medical profession.” Ex. 91, AR 139588 (AMA Comment).²⁹ Specifically regarding the agency’s expansive definition of “discrimination,” HHS entirely failed to consider or address the Final Rule’s implication for standards of professional ethics, by permitting an employee to object to a wide range of health care services at any time—without notice, even in emergency contexts—with no affirmative duty to disclose that objection or provide advance notice of any intent to object. *See supra* Part II.C.3.a.

Regarding the definitions of “referral” and “assist in the performance,” the Final Rule’s combination of these terms *itself* violates principles of medical ethics. The Final Rule identifies “referral” as an action that “may” constitute “assist[ance] in the performance” and thus form the basis of a protected objection. *See* 84 Fed. Reg. at 23,188-89. Yet this combination turns a basic principle on its head. As the AMA communicated to HHS, the provision of information about options for treatment is a method by which the health professions balance ethical duties, *i.e.*, allowing a practitioner to honor her own religious convictions about a health procedure, while simultaneously fulfilling her duty of care to a patient. *See* Ex. 91, AR 139587-88 (AMA Comment). AMA’s Code directs physicians to “inform the patient about all relevant options for treatment, including options to which the physician morally objections,” and should a physician decline to offer a referral, the physician should, at minimum, “offer impartial guidance to

²⁹ See, e.g., 84 Fed. Reg. at 23,171, 23,174-77, 23,181, 23,183, 23,189, 23,199-200, 23,204, 23,208, 23,246, 23,249-250.

patients about how to inform themselves regarding access to desired services.”

Yet the Final Rule prevents this carefully calibrated balancing of ethical duties. Its definition of “referral” includes the “provision of information in oral, written, or electronic form” where “the purpose or reasonably foreseeable outcome . . . is to assist a person” in “obtaining . . . a particular health care service.” 84 Fed. Reg. at 23,203. But if a patient “desires” a service—as stated in the AMA Code—it is a reasonably foreseeable outcome that the health service will result from a physician providing the patient guidance on how to inform herself on access—*e.g.*, from providing information resources. Thus, as HHS was well aware, the Final Rule’s definition of “referral” expressly permits a doctor to object to her minimally required ethical duty under the AMA’s Code. *See id.* at 23,253 (noting information the Final Rule “may allow” providers to abstain from providing).

Where HHS purports to address providers’ duties to patients in the Final Rule—or the balancing of these duties described above—it does so in conclusory fashion. Referring generally to comments about the Final Rule and principles of informed consent, HHS pastes a near-verbatim answer into its discussions of both “assist in the performance” and “referral.” The agency states that “medical ethics have long protected rights of conscience alongside the principles of informed consent” and, accordingly, it “does not believe that enforcement of conscience protections . . . violates or undermines the principles of informed consent.” 84 Fed. Reg. at 23,200; *see also id.* at 23,189. Yet HHS sidesteps the fact that the Final Rule’s definitions are precisely what undermine the method by which medical ethics harmonized those principles, as discussed above. HHS knew this, because the professional organizations that developed this method clearly stated it to the agency. HHS’s “belief” reflects a complete failure to address the Final Rule’s conflict with medical ethics or, at the least, the absence of a

“reasoned analysis” and “satisfactory explanation of its action.” *State Farm*, 463 U.S. at 42-43.

e. HHS failed adequately to explain its departure from Title VII’s framework for workplace religious accommodation.

The Final Rule is also arbitrary because, in departing without adequate rationale from the framework for religious accommodations in the workplace provided by Title VII of the Civil Rights Act of 1964, the Final Rule is not based on a “reasoned analysis” indicating that HHS “examine[d] the relevant data and articulate[d] a satisfactory explanation of its action.” *State Farm*, 463 U.S. at 42-43. In failing to explain why existing remedies against discrimination are insufficient, the Department has not met its “duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives.” *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 & n.46 (D.C. Cir. 1987) (internal quotation marks omitted).

Title VII has long governed the assessment of claims for religious accommodations in the workplace, with a central focus on a balancing of all interests at stake. Existing employment discrimination law requires employers to accommodate employees’ religious beliefs “unless an employer demonstrates that he is unable to reasonably accommodate to an employee’s or prospective employee’s religious observance or practice without undue hardship on the conduct of the employer’s business.” 42 U.S.C. § 2000e(j); *see also id.* § 2000e-2(a); 29 C.F.R. § 1605.2 (discussing reasonableness and undue hardship). This framework permits an employer simultaneously to consider the needs of the requesting employee, other employees, and its business and customers—in this context, patients in need of care.

Title VII thus protects individuals’ religious beliefs while balancing employers’ and employees’ interests. The Final Rule departs from this framework uniquely in the context of the refusal-of-care statutes, but the Department has not explained why a departure from the Title VII

framework—to which Plaintiffs have long conformed their employment practices—is necessary. First, the definition of “discrimination,” at subsection (5), prohibits an employer from inquiring, pre-hire, whether a prospective employee objects to performing or assisting in types of work, making it impossible for the employer to determine whether hiring that individual would pose an undue hardship on the business—*i.e.*, if the individual is unwilling to perform core job functions. *See* 84 Fed. Reg. at 23,263. Second, the definition, at subsection (4), provides that an employer does not discriminate when it offers and an objecting employee “voluntarily accepts an effective accommodation”—thus providing an employee a veto right over accommodation. *Id.* Under Title VII, an employee does not have this unilateral right to a religious accommodation of his or her choosing at the expense of all the other interests at play in the workplace.

Indeed, HHS concedes that it rejected “incorporating the additional concept of an ‘undue hardship’ exception for reasonable accommodations under Title VII.” *Id.* at 23,191. But the agency dodges any reasoned explanation for this rejection, and instead merely asserts its belief that, because Congress “did not adopt an undue hardship exception” expressly within the various conscience protection statutes interpreted by the Final Rule, this reflects a legislative intent “to take a different approach.”³⁰ *Id.* However, Congress’s “silence in this regard can be likened to the dog that did not bark,” and should not be interpreted as an intent to depart from Title VII’s established framework for religious discrimination claims. *Miller v. Clinton*, 687 F.3d 1332, 1350 (D.C. Cir. 2012) (internal quotation marks omitted) (rejecting claim that silence in Basic Authorities Act altered provisions of Age Discrimination in Employment Act); *see also* Provider

³⁰ HHS argues that this purported legislative intent is “consistent with the fact that Title VII’s comprehensive regulation of American employers applies in far more contexts, and is more . . . potentially burdensome . . . than the more targeted conscience statutes that are the subject of this rule,” *id.*, apparently overlooking the fact that the agency’s inclusion of “plan sponsor” in the definition of “health care entity” sweeps within the Final Rule’s ambit virtually any employer that offers health insurance to its employees. *See* 84 Fed. Reg. at 23,195.

SJ Mem., Parts II.A.1, IV.

HHS's reliance on this congressional silence likewise does not constitute a reasoned analysis or satisfactory explanation for departing from a legislative policy that has set the standard for workplace religious accommodation for decades. *See City of Brookings Mun. Tel. Co.*, 822 F.2d at 1169 & n.46 ("[T]he failure of an agency to consider obvious alternatives has led uniformly to reversal."); *Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216, 1218 (D.C. Cir. 1983) (agency's decision failed to give sufficient consideration to narrower alternatives). To the contrary, "[a]nother shadow is cast when agency action, not clearly mandated by the agency's statute, begins to encroach on congressional policies expressed elsewhere." *Cape May Greene, Inc. v. Warren*, 698 F.2d 179, 190 (3d Cir. 1983) (holding EPA action arbitrary and contrary to law for "failure to give sufficient weight to congressional admonition in the Coastal Zone Management Act"). HHS's failure to explain why Title VII's framework is insufficient to address the harms the refusal-of-care statutes seek to prevent is arbitrary and capricious.

4. The Department's analysis of the costs and benefits of the Final Rule is counter to the evidence before the agency.

The Final Rule should be vacated as arbitrary and capricious for the independent reason that the Department relied on a cost-benefit analysis so flawed that it cannot be viewed as anything other than an effort to "put a thumb on the scale" by overvaluing the benefits and undervaluing the costs. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008); *see* Pls.' PI Mem. 38-43; Provider PI Mem. 23-24; Br. of the Inst. for Policy Integrity as *Amicus Curiae* 4-24, Dkt. 52-1 (filed June 21, 2019).

The Department casts this detailed presentation of the many flaws in its quantitative and qualitative analysis as nothing more than Plaintiffs' preference "to impose their own standard of

research on the agency before it can act.” Defs.’ Mem. 57. Not so: the “consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act,” *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732-33 (D.C. Cir. 2016); and agency action is invalid where it “fail[s] to adequately account” for relevant costs and benefits. *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 53-55 (D.D.C. 2019).

For example, Plaintiffs identified the agency’s significant mistake in underestimating the number of covered persons and entities, *see* Pls.’ PI Mem. 41-42: the agency concluded that the Final Rule may increase the number of regulated entities by only about 0.02%, *see* 84 Fed. Reg. at 23,233-35 & tbl.2, even though the Final Rule’s definition of “health care entity” both expands *and was intended to expand* the number of regulated persons and entities considerably. *See id.* at 23,194-96, 23,264 (§ 88.2). This is a significant miscalculation that results in a failure to present the true costs of the Department’s policy choice. Yet Defendants’ only response is that ‘New York provides no alternative evidence of its own” regarding the number of covered entities. Defs.’ Mem. 59-60. But the administrative record that was before the agency when it was developing the Final Rule did provide the agency ample evidence of the expanded universe of regulated entities the rule’s definitions would encompass.³¹ And it is the agency’s obligation to account for those costs, and show that it “examine[d] the relevant data” and can “articulate . . . a rational connection between the facts found and the choice made.” *State Farm*, 463 U.S. at 43; *Council of Parent Attorneys & Advocates*, 365 F. Supp. 3d at 54-55.

The Department finally seeks to excuse its inadequate cost-benefit analysis by protesting that “[m]any of these questions . . . are difficult to answer.” Defs.’ Mem. 60. But “[a]n agency

³¹ E.g., Ex. 68, AR 52459 (Comment, N.Y. Dep’t of Fin. Servs.); Ex. 91, AR 139587 (AMA Comment); Ex. 96, AR 140265 (BCBS Comment); Ex. 97, AR 140350 (CA Insur. Comment); Ex. 113, AR 160751 (PPFA Comment); Ex. 116, AR 161178 (IPI Comment).

may not avoid an obligation to analyze . . . consequences that foreseeably arise from [its action] merely by saying that the consequences are unclear" *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002). The Department's "conclusory statements" regarding the costs and benefits of the Final Rule do not constitute reasoned decisionmaking. *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986).

III. The Final Rule is unconstitutional.

A. The Final Rule violates the constitutional separation of powers.

The Constitution vests the spending power in Congress. U.S. Const. art. I, § 8, cl. 1. The Executive Branch "does not have unilateral authority to refuse to spend . . . funds" already appropriated by Congress. *In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013).

In the context of the refusal statutes, Congress has chosen to tailor the conditions it has placed on the receipt of federal funds to specific procedures, involvement in those procedures, and health care providers or entities. *See* Pls.' PI Mem. 44-45. Defendants' wholesale refusal to address this argument is telling, especially because Defendants cannot dispute that the text of the Final Rule allows HHS to withhold all of the federal funding that Plaintiffs receive from the Department based on any perceived violation of any of the underlying statutes that it purports to implement. *See* Fed. Reg. at 23,272 (§ 88.7(i)(3)(i)-(iii)).

Although Congress may delegate some discretion to the Executive Branch to decide how to spend appropriated funds, *see Clinton v. City of New York*, 524 U.S. 417, 488 (1998), this discretion is cabined by the scope of the delegation, *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). When Congress provides agencies with broad authority to withhold funds, it does so clearly. *See* Providers' SJ Mem., Part I. Defendants cannot find support in any of the underlying statutes for HHS's claim of broad power to terminate all federal funding. For example, the Weldon Amendment—on which Defendants rely—does not even mention HHS, let alone

expressly grant the Department this authority. Defs.’ Mem. 71. Simply put, “Congress does not hide elephants in mouseholes.” *Cyan, Inc. v. Beaver Cty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1071-72 (2018) (internal quotation marks omitted).

B. The Final Rule violates the Spending Clause.

The Final Rule violates the Spending Clause because it (1) attaches retroactive and ambiguous conditions to Plaintiffs’ receipt of federal funds; (2) is coercive; (3) lacks a nexus between the funds at issue and the Final Rule’s purpose; and (4) induces Plaintiffs to engage in unconstitutional violations of the Establishment Clause. Pls.’ PI Mem. 45-53; *see South Dakota v. Dole*, 483 U.S. 203, 207-08, 211 (1987).

Defendants’ assertion that Plaintiffs’ “real objection is to the underlying substantive law,” Defs.’ Mem. 60-61, is incorrect—Plaintiffs argue that the Final Rule substantially departs from the underlying statutes that it purports to implement by, among other things, redefining and dramatically expanding key definitions within those statutes, and threatening the termination of all HHS funds for a perceived violation of a new regime that HHS creates out of whole cloth. Plaintiffs’ challenge is not to Congress’s authority to enact the underlying statutes that Plaintiffs have complied with for years; it is instead to HHS’s legislative fiat to create a new federal conscience regime in violation of the Spending Clause.

1. Plaintiffs did not knowingly accept the new and confusing conditions imposed by the Final Rule.

The Final Rule violates the Spending Clause’s requirement to provide clear notice to Plaintiffs by retroactively and ambiguously imposing conditions on the receipt of federal funds. Pls.’ PI Mem. 46-50. *See Dole*, 483 U.S. at 203 (explaining that when conditions are placed on federal funds it must be done “unambiguously” so that states and local jurisdictions determining whether they agree to accept such funds may “exercise their choice knowingly, cognizant of the

consequences of their participation”).

“States cannot knowingly accept conditions of which they are ‘unaware’ or which they are ‘unable to ascertain.’” *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). The Final Rule violates both of these principles. First, as Plaintiffs explained in detail in their opening brief, the Final Rule contorts the underlying statutes that it purports to implement to such a degree that Plaintiffs were not and could not have been aware of the new conditions when agreeing to accept the relevant funding. Specifically, the Final Rule (1) includes new definitions of key terms in the underlying statutes that dramatically expand the scope of those statutes; (2) imposes new, retroactive, and burdensome compliance requirements that apply immediately to all recipients of federal funds; (3) disregards that Congress in the relevant statutes conditioned funding from specific sources with specific prohibitions; and (4) purports to conflict with literally dozens of state and local laws on a variety of substantial issues related to health and patient care. Pls.’ PI Mem. 47-48.

Defendants fail to address the import of any of these new conditions, and instead claim confusion as to the meaning of “retroactive.” Defs.’ Mem. 63. But as the Supreme Court has explained, “though Congress’s power to legislate under the spending power is broad, it does not include surprising participating States with post-acceptance or retroactive conditions.” *NFIB*, 567 U.S. at 584 (alterations and internal quotation marks omitted); *see also Mayhew v. Burwell*, 772 F.3d 80, 88 (1st Cir. 2014) (“[T]he anti-retroactivity rule . . . provides that Congress may not surprise states . . . with post-acceptance or retroactive conditions.” (alterations and internal quotation marks omitted)). This is exactly what the Final Rule does. Pls.’ PI Mem. 47-48. Indeed, Plaintiffs “could hardly anticipate that” HHS would claim authority to patch together

thirty statutes on a variety of topics scattered throughout the United States Code and appropriations riders to “transform” the landscape of health care provision and regulation “so dramatically.” *NFIB*, 567 U.S. at 584; *see also Cty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 532 (N.D. Cal. 2017) (where conditions are not “unambiguous condition[s] that the states and local jurisdictions voluntarily and knowingly accepted at the time Congress appropriated these funds, [they] cannot be imposed”).

Second, the Final Rule is ambiguous in that it fails to make clear what conduct it prohibits or requires, what funding streams are at stake, and how recipients can avoid its penalties. *See Pls.’ PI Mem.* 48-50. Rather than attempt to defend or clarify *any* of the Final Rule’s opaque requirements, Defendants merely state, without support or explanation, that the Final Rule is “necessarily clearer and less ambiguous than the statutes.” *Defs.’ Mem.* 62. Defendants are wrong. For example, in sharp contrast to the underlying statutes, the Final Rule expands the scope and applicability of federal conscience protections in a way that significantly disrupts health care and creates an unworkable morass of potentially-life threatening situations for Plaintiffs. *See Pls.’ PI Mem.* 15-30; *Provider SJ Mem.*, Part II.A. Moreover, again in contrast to the underlying statutes, Plaintiffs have the impossible task of reconciling the Final Rule’s requirements with conflicting provisions of other laws like EMTALA and Section 1554 of the ACA. *See Provider SJ Mem.*, Parts II.A, II.B, II.D. And unlike the underlying statutes—which clearly identify the funds at stake for violations of the statutes—Plaintiffs stand to lose all HHS funds for any perceived misstep under the Final Rule.

Defendants’ nearly singular reliance on the Ninth Circuit’s decision in *Mayweather v. Newland*, 314 F.3d 1062 (9th Cir. 2002) is misplaced. *Defs.’ Mem.* 62-63. First, Plaintiffs take no issue with the fact that Congress may exercise its Spending Clause power to foster religious

freedom and deter religious-based discrimination. *Id.* at 62. As *Mayweathers* makes clear, however, in advancing these interests the limitations to the Spending Clause power—the same limitations that the Final Rule violates here—apply. *See Mayweathers*, 314 F.3d at 1066. Second, unlike the plaintiffs in *Mayweathers*, Plaintiffs here do not challenge Congress’s “express conditional language” as “perhaps unpredictable.” *Id.* at 1067. Instead, Plaintiffs challenge Defendants’ contortion of clear and well-settled statutory conditions because they are unworkable, nonsensical, and contrary to both the statutes HHS purports to interpret and others on which Plaintiffs rely and with which they must comply.

HHS falls “well short of providing clear notice to [Plaintiffs] that they, by accepting funds . . . would indeed be obligated to comply” with Defendants’ radical departure from congressional intent and the status quo. *Pennhurst*, 451 U.S. at 25. For these reasons, Plaintiffs could not have “exercise[d] their choice” to accept funds “knowingly, cognizant of the consequences of their participation.” *Dole*, 483 U.S. at 203 (internal quotation marks omitted).

2. The Final Rule creates a new program and coerces Plaintiffs to comply.

The Final Rule also violates the Spending Clause because far from “creat[ing] incentives for [Plaintiffs] to act in accordance with federal policies,” its “financial inducement . . . is a gun to the head.” *NFIB*, 567 U.S. at 577, 581 (internal quotation marks omitted); *see* Pls.’ PI Mem. 50-51.

Defendants’ attempts to distinguish *NFIB* fall flat. First, as Plaintiffs explained in their opening brief, the Final Rule creates an entirely new regime that accomplishes “a shift in kind, not merely degree.” *NFIB*, 567 U.S. at 583; *see* Pls.’ PI Mem. 51. Defendants’ only response is to once again point to the fact that the underlying statutes have been in effect for decades. Defs.’ Mem. 65. This is no answer at all. *See NFIB*, 567 U.S. at 541 (noting Medicaid’s enactment in

1965, and analyzing whether its expansion was coercive). Instead, the relevant inquiry is whether the challenged provisions have expanded those in the original statute to such a degree as to create a new program. *Id.* at 583. The Final Rule does just that: it weaves together disparate and distinct anti-discrimination prohibitions, 84 Fed. Reg. at 23,264-69 (§ 88.3); redefines terms to include newly covered individuals, entities, and procedures, *id.* at 23,263-64, (§ 88.2); and creates a compliance and enforcement scheme that substantially alters Congress's efforts to tailor specific requirements to specific sources of funds, *id.* at 23,269-72 (§§ 88.4, 88.6, 88.7). *See NFIB*, 567 U.S. at 583 (expansion of the original program “for four particular categories of” individuals beyond those categories was a shift in kind).

Second, Defendants are wrong that “it is far from clear that noncompliance with the conscience statutes and the [Final Rule] would impact all of the funding sources that New York identifies.” Defs.’ Mem. 64. The Final Rule’s enforcement scheme plainly threatens billions of dollars in funding that Plaintiffs receive for a failure or suspected failure to comply with its provisions and those of the underlying statutes. Specifically, the Final Rule’s enforcement scheme allows the Department to initiate a compliance review or a complaint investigation of Plaintiffs if it “suspect[s]” noncompliance. 84 Fed. Reg. at 23,271 (§§ 88.7(c),(d)). If the Department determines that “there is a failure to comply” with any provision of the Final Rule or the statutes it implements, the Department may refer the matter to the Department of Justice for enforcement, or the Department may itself withhold, deny, suspend, or terminate federal funds. *Id.* at 23,271-72 (§§ 88.7(h), (i)(3), (j)). The compliance process for the Department to follow is described by citations to three disparate administrative procedures. *Id.* at 23,272 (§ 88.7(i)(3)). And no matter Defendants’ assurance that “HHS will always begin by trying to resolve a potential violation . . . through informal means,” Defs.’ Mem. 64, the Department is expressly

authorized to terminate a recipient’s federal funds even *during* the pendency of good-faith voluntary compliance efforts. *Id.* at 23,271-72 (§ 88.7(i)(2)). Moreover, if the Department believes a recipient has “fail[ed] or refuse[d] to furnish an assurance or certification” required by § 88.4, the Department may suspend *all* HHS funding during any efforts at resolution and even before a finding of noncompliance. *Id.* at 23,272 (§ 88.7(j)). Accordingly, Plaintiffs stand to lose “not merely a relatively small percentage of its existing [HHS funding], but *all* of it.” *NFIB*, 567 U.S. at 581 (internal quotation marks omitted).

Plaintiff States collectively received approximately \$192 billion in federal funding from HHS in fiscal year 2018 based on publicly available information from the Department’s Tracking Accountability in Government Grants System (“TAGGS”).³² This funding is critical to a wide range of essential programs and services that Plaintiffs use to promote the health and well-being of their residents, including: (1) Medicaid and the Children’s Health Insurance Program;³³ (2) services to promote the health of women, infants, and children;³⁴ (3) family planning and contraception;³⁵ (6) treatment of substance use disorders;³⁶ (7) treatment and screening for arthritis, asthma, and other cancers, and heart disease;³⁷ (8) medical services to

³² See Ex. 136 (TAGGS Recipient Search). Plaintiffs generated this number by filtering “Fiscal Year” to “2018,” “Recipient Class” to “State Government,” and “State” to each State Plaintiff represented in this lawsuit. The Court may take judicial notice of this publicly available material, *see Force v. Facebook, Inc.*, No. 18-397, 2019 WL 3432818, at *3 n.5 (2d Cir. July 31, 2019), and Defendants also rely on data from TAGGS to justify the Final Rule, *see, e.g.*, 84 Fed. Reg. at 23,232 & n.182, 23,235-36 & n.224.

³³ See Ex. 1 (Adelman Decl.) ¶ 5; Ex. 5 (Allen Decl.) ¶ 8; Ex. 11 (Clark Decl.) ¶ 8; Ex. 20 (Forsaith Decl.) ¶¶ 7, 10; Ex. 33 (Miller Decl.) ¶¶ 14, 16-18; Ex. 38 (Rosen Decl.) ¶ 7; Ex. 44 (Turnage Decl.) ¶ 7; Ex. 47 (Zimmerman Decl.) ¶ 7; Ex. 48 (Zucker Decl.) ¶¶ 93-94.

³⁴ See Ex. 9 (Brancifort Decl.) ¶ 16; Ex. 15 (Elnahal Decl.) ¶ 9; Ex. 17 (Ezike Decl.) ¶¶ 25-29; Ex. 19 (Foley Decl.) ¶¶ 5-6; Ex. 20 (Forsaith Decl.) ¶ 8; Ex. 28 (Levine Decl.) ¶¶ 11-14;

³⁵ See Ex. 2 (Alexander-Scott Decl.) ¶ 9; Ex. 10 (Charest Decl.) ¶¶ 3, 5; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 35 (Oliver Decl.) ¶ 5; Ex. 37 (Rattay Decl.) ¶ 15; Ex. 42 (Swartz Decl.) ¶ 8.

³⁶ See Ex. 15 (Elnahal Decl.) ¶ 11; Ex. 20 (Forsaith Decl.) ¶¶ 7, 9; Ex. 28 (Levine Decl.) ¶ 28(vi); Ex. 40 (Sherych Decl.) ¶ 7; Ex. 44 (Turnage Decl.) ¶ 8.

³⁷ See Ex. 2 (Alexander-Scott Decl.) ¶ 8; Ex. 9 (Brancifort Decl.) ¶ 15; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 28

residents with HIV;³⁸ (9) funds for bioterrorism and Ebola preparedness, and other disaster response;³⁹ (10) student health services;⁴⁰ and (11) biomedical and health-related research, education, and training funds to universities.⁴¹ Plaintiffs simply cannot gamble away some or all of this funding by hoping the Department will exercise with restraint its expansive authority under the Final Rule to withhold these funds in full. *Cf. United States v. Stevens*, 559 U.S. 460, 480 (2010) (“We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly.”).

Finally, Defendants’ protest that Plaintiffs cannot succeed on a “facial challenge by identifying a handful of implausible and speculative circumstances” that “*might* have a coercive effect,” Defs.’ Mem. 66, fail for the same reason. The Final Rule’s provisions and the authority that they provide to HHS are real, and they are currently set to take effect in only a few months. Nor do Plaintiffs take comfort in Defendants’ note that HHS has never terminated substantial funding before. *Id.* Far from offering any reassurances that it will exercise restraint, HHS has made clear that it issued the Final Rule precisely *because* of “[i]nadequate enforcement tools to address unlawful discrimination and coercion,” 84 Fed. Reg. at 23,228, without offering any explanation for why the tools it had—including informal resolution of complaints—were inadequate. *See supra* Part II.C.1. Accordingly, any nod to past HHS practice is irrelevant.

More fundamentally, Defendants’ argument misunderstands the Spending Clause’s constraint on the agency’s rulemaking authority. The constitutional prohibition on coercion does

(Levine Decl.) ¶ 14.

³⁸ See Ex. 5 (Allen Decl.) ¶ 8; Ex. 7 (Anderson Decl.) ¶ 8; Ex. 15 (Elnahal Decl.) ¶¶ 7-8; Ex. 17 (Ezike Decl.) ¶¶ 33-35.

³⁹ See Ex. 28 (Levine Decl.) ¶¶ 14, 28(ii), 28(iv); Ex. 35 (Oliver Decl.) ¶ 7; Ex. 46 (Wagaw Decl.) ¶ 6.

⁴⁰ HIV/STD prevention, contraception, and abortion referrals, *see* Ex. 24 (Hirata Decl.) ¶¶ 5-7; Ex. 34 (Nichols Decl.) ¶¶ 5-7.

⁴¹ See Ex. 22 (Hedges Decl.) ¶ 6; Ex. 23 (Herbst Decl.) ¶¶ 13-14; Ex. 29 (Lucchesi Decl.) ¶ 7.

not spring into effect only after the devastating consequences Plaintiffs confront because of the Final Rule—*i.e.*, the termination of substantial amounts of federal health care funds—come to fruition. Instead, it is the *threat* of terminating those funds that the limitations on the spending power proscribe. *See NFIB*, 567 U.S. at 580 (underscoring concerns with respect to the “nature of the threat” posed by the Medicaid provisions of the Affordable Care Act); *see also id.* (explaining that “[b]y financial inducement the Court meant the *threat* of losing . . . funds” (emphasis added)). This threat in the form of “economic dragooning” leaves Plaintiffs with “no real option but to acquiesce” in the Final Rule’s new regime. *Id.* at 582.

3. The Final Rule violates the Spending Clause’s relatedness requirement.

As Plaintiffs explained, through the Weldon Amendment, the Final Rule appears to condition the receipt of billions of dollars of federal funds that are entirely unrelated to health care on compliance with its provisions. Pls.’ PI Mem. 51-52. This violates the Spending Clause’s requirement that any conditions imposed on spending must be related “to the federal interest in . . . [the] program[.]” *Dole*, 483 U.S. at 207 (internal quotation marks omitted); *see also City & Cty. of San Francisco v. Sessions*, 349 F. Supp. 3d 924, 959-61 (N.D. Cal. 2018).

Defendants do not even attempt to dispute that by its terms, the Final Rule threatens federal funds not only from HHS but from the Department of Labor and the Department of Education as well. Nor do they defend that these funds have anything at all to do with the federal conscience statutes. Instead, Defendants’ only response is an unsupported suggestion that Plaintiffs have an evidentiary burden to show Labor or Education funds “will actually be at risk.” Defs.’ Mem. 67. To the extent that Defendants suggest that HHS can constitutionally force Plaintiffs to choose whether to acquiesce to the Final Rule’s provisions or take the risk that

HHS will terminate the Labor Department and Education Department funds the Final Rule authorizes it to do, this argument fails. *See supra* Part III.B.2.

4. The Final Rule violates the Spending Clause’s prohibition on unconstitutional conditions.

For the reasons explained in the Provider Plaintiffs’ summary judgment memorandum and Plaintiffs’ preliminary injunction memorandum, the Final Rule requires Plaintiffs to engage in conduct that would violate the Establishment Clause, thus violating the Spending Clause’s prohibition on unconstitutional conditions. *See* Provider SJ Mem., Part II.E; Pls.’ PI Mem. 53.

C. The Final Rule violates the Establishment Clause.

For the reasons explained in the Provider Plaintiffs’ summary judgment memorandum and Plaintiffs’ preliminary injunction memorandum, the Final Rule is unconstitutional because it impermissibly advances religious beliefs in violation of the Establishment Clause. *See* Provider SJ Mem., Part II.E; *see also* Pls.’ PI Mem. 29-30, 53.

IV. Plaintiffs are entitled to a preliminary injunction before the effective date of the Final Rule.

For the reasons set out herein (as well as in the Provider Plaintiffs’ summary judgment memorandum and Plaintiffs’ preliminary injunction memorandum), Plaintiffs are entitled to summary judgment that the Final Rule is invalid and should be set aside. The Court recognized, however, that the scale of the administrative record or other factors “may prevent a reliable final determination on the merits” before the Final Rule’s current effective date of November 22, 2019. Dkt. 121. Plaintiffs request that in the event the Court determines not to enter final judgment on the merits before November 22, the Court should in the alternative grant Plaintiffs’ request for provisional relief, and enjoin Defendants from implementing the Final Rule pending ultimate resolution of the merits. Plaintiffs are entitled to a preliminary injunction because they will suffer irreparable harm absent provisional relief; they are likely to succeed on the merits;

and the balance of equities and public interest favor a preliminary injunction.⁴²

A. The Final Rule irreparably harms Plaintiffs.

1. Plaintiffs are irreparably harmed by “the Hobson’s choice” of “whether to suffer this injury or else decline much-needed grant funds.” *New York v. U.S. Dep’t of Justice*, 343 F. Supp. 3d 213, 244 (S.D.N.Y. 2018); *see* Pls’ PI Mem. 9-14. Defendants argue that the efforts Plaintiffs must undertake to comply with the Final Rule are merely “ordinary compliance costs [that] are typically insufficient to constitute irreparable harm.” Defs.’ Mem. 75 (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005)); *see also* CMDA Mem. 5. But Plaintiffs have documented why compliance-related harms are unique here: in addition to the time, administrative burdens, and money that cannot be recouped, any changes Plaintiffs make to their policies and procedures before the Final Rule’s effective date could have irreversible effects on the health of Plaintiffs’ residents.⁴³

Defendants also argue—citing no authority—that this forced choice fails to establish irreparable injury because “a long chain of events” would have to take place before fund termination could occur. Defs.’ Mem. 75. Defendants’ argument misses the point: the “long chain of events” they describe entail efforts to modify Plaintiffs’ practices to comply with the Final Rule through measures short of fund termination, *see id.*; it is this precise compulsion—being forced to choose between changing policies to comply with an illegal regulation, or risking the loss of billions of dollars in health care funds—that causes irreparable harm to Plaintiffs. Courts have agreed, over objections identical to those Defendants raise here. *See, e.g., New*

⁴² *See Winter v. NRDC*, 555 U.S. 7, 20 (2008). For the same reasons, Plaintiffs are entitled, in the alternative, to a stay under § 705 of the APA. *See Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016).

⁴³ *See* Pls.’ PI Mem. 11-13 (noting changes that may be required to New York State’s guidance to physicians and nurse practitioners concerning statutorily-mandated provision of information to terminally ill patients about palliative and end of life care) (citing, *e.g.*, Ex. 48 (Zucker Decl.)).

York, 343 F. Supp. 3d at 244; *City of Phila. v. Sessions*, 309 F. Supp. 3d 289, 340-42 (E.D. Pa. 2018) (citing *City of Phila.*, 280 F. Supp. 3d at 655-57); *City of Chicago*, 264 F. Supp. 3d at 950; *Cty. of Santa Clara*, 250 F. Supp. 3d at 536-38. The risk of loss need not be tomorrow or absolutely assured; rather, irreparable harm is established where a plaintiff receives federal funds “knowing that the [plaintiff] *may be later deemed out of compliance with*” federal conditions on those funds. *City of Phila.*, 280 F. Supp. 3d at 656 (emphasis added); *see Pls.’ PI Mem. 11 n.9.*

2. Plaintiffs are also harmed by the damage the Final Rule will cause to their health institutions and direct delivery of health care. Defendants contend that Plaintiffs’ evidentiary showing is “purely speculative and based on a misunderstanding of what the Federal Conscience Statutes and the Rule actually require.” Defs.’ Mem. 74. But the grave operational harms identified in the dozens of declarations from Plaintiffs’ health providers and other fact witnesses are concrete and specific, not speculative. *See Pls.’ PI Mem. 15-22.*⁴⁴ Instead of addressing Plaintiffs’ evidence, HHS merely restates snippets of the Final Rule—for example, tautologically arguing that an objecting employee could not cause a staffing problem because Plaintiffs are allowed to accommodate the employee by moving her, as long as she voluntarily accepts the move, but is under no obligation to do so, no matter how reasonable. Defs.’ Mem. 74.

HHS similarly argues that a need for advance notice of an objection poses no problem for Plaintiffs as health providers, because they may require an employee to inform them of an

⁴⁴ These declarants include national leaders in their respective fields whose written testimony is supported by detailed and specific evidence. *See Exs. 1-48.* Defendants have not contested a single paragraph from this written testimony, and have conceded that they will not seek to cross-examine a single witness at the preliminary injunction hearing in this matter. *See Paragraphs 3(K) and 5(C)(i) of this Court’s Individual Rules and Practices.* Intervenors separately quibble at the margins with the likelihood that a particular physician will object to treating a woman with an ectopic pregnancy, or Plaintiffs’ lack of identifying a specific ambulance driver or helicopter pilot who has made a religious objection in the past. CMDA Mem. 5-6, 9. These arguments again miss the point detailed by declarants from numerous hospital systems: they have policies in place requiring sufficient advance notice of religious objections to *avoid* crises that arise when objections are made at the time a patient needs treatment, and it is precisely these policies that the Final Rule limits and undermines to the point of inoperability. *See Pls.’ PI Mem. 15-22.*

objection—leaving out the fact that the Final Rule permits this to happen only once a year (barring an undefined “persuasive justification”), and places no duty upon the employee to inform the employer of any change in the employee’s religious views over the course of that year. But HHS remains silent as to how such a rule could safely be implemented in sensitive emergency or medical transit settings, or in rural settings with personnel shortages, though Plaintiffs documented their imminent injuries in just these settings. *See* Pls.’ PI Mem. 18-20.⁴⁵

3. Finally, the Final Rule irreparably injures Plaintiffs as regulators and insurers. *See* Pls.’ PI Mem. 22-23. These injuries alone support injunctive relief, because “a state’s inability to implement its laws constitutes irreparable harm.” *New York*, 351 F. Supp. 3d at 675-76 (citing *Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018)). Defendants’ and Intervenors’ oppositions to preliminary injunction did not contest or respond at all to this showing of irreparable harm, Defs.’ Mem. 73-76, CMDA Mem. 5-10, thereby conceding these injuries. *See, e.g., Rodriguez v. Carson*, No. 17-cv-4344, 2019 WL 3817301, at *4 (S.D.N.Y. Aug. 14, 2019) (holding that a party’s failure to raise an issue in an opposition brief waives the issue).

B. Plaintiffs are likely to succeed on the merits of their claims.

Plaintiffs have also established the required merits showing to entitle them to preliminary relief. In the Second Circuit, Plaintiffs may obtain a preliminary injunction by showing irreparable harm and either a likelihood of success on the merits or “sufficiently serious questions going to the merits to make them a fair ground for litigation” *Citigroup Glob. Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (quoting *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979)).

⁴⁵ HHS later argues that Plaintiffs assert harms against third parties, citing to a discussion of Plaintiffs’ direct delivery of health care. *See* Defs.’ Mem. 76. As discussed, Plaintiffs directly provide care as operators of health institutions, and administer insurance laws as health regulators; both such functions are impeded by the Final Rule.

For the reasons already briefed, Plaintiffs are likely to succeed on the merits of their claims that the Final Rule violates the APA and the Constitution. *See supra* Parts II, III; *see also* Pls.’ PI Mem. 24-53; Provider SJ Mem., Parts I, II, III. In addition, given the overwhelming evidence that the “balance of hardships tip[s] decidedly” in Plaintiffs’ favor—as discussed above and as Defendants hardly contest—this Court may also apply the “serious questions” standard and conclude that if nothing else, Plaintiffs have presented “a fair ground for litigation” on the merits. Under either standard, Plaintiffs readily clear the showing required for preliminary relief.

C. The balance of equities and public interest favor preliminary injunctive relief.

As to the final factors for a preliminary injunction, “there is a substantial public interest ‘in having governmental agencies abide by the federal laws that govern their existence and operations.’” *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). Defendants argue that the federal government suffers irreparable injury if it is “enjoined by a court from effectuating statutes enacted by representatives of its people.” Defs.’ Mem. 76 (quoting *Maryland v. King*, 133 S. Ct. 1, 3 (2012)). But as Defendants point out repeatedly, Plaintiffs have not challenged the underlying refusal statutes, *see* Defs.’ Mem. 1, 3, 61, 65-68, so there is no risk those statutes will be enjoined. Nor can the Department support its claim of injury where it asserts continuing investigative and enforcement authority under the refusal statutes independent of the Final Rule. *See* Defs.’ Mem. 80; *see also* 76 Fed. Reg. at 9975 (acknowledgment in the 2011 Final Rule that “none of these statutory provisions require promulgation of regulations for their interpretation or implementation”).

Intervenors claim that an injunction would cause their members distinct injury because they object to procedures on religious grounds, *see* CMDA Mem. 10-12, yet they fail to (1)

address that the refusal statutes will not be enjoined by this action, or (2) allege any instance of discrimination a member has faced, other than the general results of a survey cited in the Final Rule’s preamble, the flaws of which have been addressed previously.⁴⁶ See Pls.’ PI Mem. 40-41.

The Court should therefore grant Plaintiffs’ motion for preliminary injunction.

V. Plaintiffs are entitled to vacatur of the Final Rule as well as declaratory and injunctive relief to remedy Defendants’ violations of the APA and the Constitution.

A. The Court should vacate the Final Rule.

The APA mandates that the Court “shall” “hold unlawful and set aside agency action” that is arbitrary and capricious, contrary to law, or in excess of the agency’s statutory authority. 5 U.S.C. § 706(2)(A), (C). When a regulation is not promulgated in accordance with the APA, challengers are “entitled to relief under that statute, which normally will be a vacatur of the agency’s [decision].” *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001).

Vacatur is the appropriate remedy under the APA both when an agency acts contrary to law, e.g., *NRDC v. EPA*, 489 F.3d 1250, 1261 (D.C. Cir. 2007) (vacating rule that “conflicts with the plain meaning of the statute”), and when an agency action is arbitrary and capricious, e.g., *Camp v. Pitts*, 411 U.S. 138, 143 (1973) (“If [the agency’s] finding is not sustainable on the administrative record made, then the [agency’s] decision must be vacated . . .”). Vacatur

⁴⁶ Intervenors now attempt to shoehorn in the results of a new survey that post-dates the Final Rule, is not part of the administrative record, and cannot, therefore, be used to uphold the Final Rule. See CMDA Mem. 10-12; Norman Decl., Dkt. 153. The Court should also disregard this new evidence in light of Intervenors’ failure to comply with Rule 56(c)(4), which requires a declaration to “set out facts that would be admissible in evidence.” The Norman Declaration fails to do so because either: (1) it is opinion testimony that fails to meet the standard for such testimony, see Fed. R. Evid. 702, and Intervenors failed to fulfill the disclosure requirements of Rule 26, see Fed. R. Civ. P. 26(a)(2); or, alternatively, (2) it is opinion testimony by a lay witness, only admissible if it is “rationally based on the witness’s perception,” and “not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.” Fed. R. Evid. 701(a), (c). The Norman Declaration fails both requirements, and especially 701(c), because public opinion polling and survey methodology are clearly “scientific, technical, or other specialized knowledge within the scope of Rule 702.” See, e.g., *United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (if the purported lay opinion “rests in any way upon scientific, technical, or other specialized knowledge, its admissibility must be determined by reference to Rule 702, not Rule 701”) (quoting 4 Weinstein’s Federal Evidence § 701.03[1]).

reflects the sound principle that an agency action that violates the APA “cannot be afforded the force and effect of law,’ and is therefore void.” *Air India v. Brien*, No. 00-cv-1707, 2002 WL 34923740, at *14 (E.D.N.Y. Feb. 14, 2002) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979)). Because the Final Rule violates both the APA and the Constitution, the Court should order the typical relief mandated by the APA and vacate the Final Rule. 5 U.S.C. § 706(2).

Contrary to Defendants’ contention, nationwide relief is the usual course in an APA action because when “agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed.” *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *see also Pennsylvania v. President of the United States*, 930 F.3d 543, 575 (3d Cir. 2019) (“[O]ur APA case law suggests that, at the merits stage, courts invalidate—without qualification—unlawful administrative rules as a matter of course Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations.”).

An order vacating the Final Rule under the APA thus inherently has nationwide application, and Defendants’ concerns about nationwide injunctive relief are misplaced. *See NAACP v. Trump*, 315 F. Supp. 3d 457, 474 n.13 (D.D.C. 2018). Nationwide relief is further required here to provide a complete remedy to the Plaintiffs in these consolidated cases, who collectively operate health centers nationwide. *See* Pls.’ PI Mem. 54-55; Provider PI Mem. 51.

B. In the alternative, the Court should order provisional relief under Rule 65(a) or 5 U.S.C. § 705.

Alternatively, if this case is not resolved on the merits by the Final Rule’s effective date, the Court should grant Plaintiffs’ request for interim equitable relief as the public interest requires, or stay the effective date of the Final Rule pending resolution on the merits, per 5 U.S.C. § 705. *See* Pls. PI Mem. 54-55.

Whether the Court proceeds to enter a preliminary injunction, or to postpone the effective date of the Final Rule pending judicial review, any relief granted would properly apply nationwide, as noted in Part V.A. The scope of preliminary injunctive relief “is dictated by the extent of the violation established.” *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Plaintiffs have demonstrated a likelihood of success on the merits, and the usual nationwide relief granted in APA actions applies here. *See Harmon*, 878 F.2d at 495 n.21; *NAACP*, 315 F. Supp. 3d at 474 n.13. This is especially true in light of “the equities of [this] case.” *California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018). Together, Plaintiffs are twenty-three state and local governments and two nationwide organizations operating hundreds of health centers in all fifty states, the District of Columbia, and the U.S. territories. Far from a case where “the record is not sufficiently developed on the nationwide impact of the [agency action],” *City & Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1245 (9th Cir. 2018), Plaintiffs have described irreparable harms that are geographically expansive in scope. *See supra* Part IV.A; *see also* Pls.’ PI Mem. 10-23. An injunction without geographic limitation is necessary to provide Plaintiffs with complete relief.

C. The Court should vacate and enjoin the Final Rule in its entirety because the challenged portions of the regulation are not severable from the remainder.

The Court should likewise reject Defendants’ skeletal suggestion to vacate or enjoin only part, but not all, of the Final Rule. Defs.’ Mem. 79-80. “Whether the offending portion of a regulation is severable depends on the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision.” *MD/DC/DE Broad. Ass’n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2000) (citation omitted). Defendants’ cursory explanation that the Final Rule covers a wide variety of statutory provisions and defines several terms that “can operate independently of one another” does not establish that the Final Rule would function if unspecified pieces of it were severed. Defs.’ Mem. 79-80. Nor have Defendants explained

how the Court “might craft a limited stay.” *Texas*, 829 F.3d at 435.

To the contrary, the Final Rule’s provisions are co-dependent, which hinders the regulation’s ability to function sensibly without all component parts. Several sections cross-reference and rely on one another. *See, e.g.*, 84 Fed. Reg. at 23,264-69 (mandating compliance with §§ 88.4, 88.6); *id.* at 23,269-70 (assurance/certification compliance requirements dependent on funds to which § 88.3 applies, and failure to submit assurances/certifications are subject to enforcement under § 88.7). And the Department makes clear that compliance with certain provisions of the Final Rule will inform its execution of its powers pursuant to other sections. *Id.* at 23,216 (“OCR will consider the posting of notices [described in § 88.5] as non-dispositive evidence of compliance . . .”). At minimum, if the Court vacates parts of the Final Rule but believes others may be severable, Plaintiffs request the opportunity to brief the issue after receiving the benefit of the Court’s judgment regarding which parts of the rule are invalid.

D. The Court should reject Defendants’ request for an advisory opinion on the lawfulness of undisclosed investigations.

Finally, the Court should reject Defendants’ invitation to opine on ongoing unspecified investigations not before the Court. Plaintiffs have challenged the Final Rule, not the underlying statutes on which the Department purportedly relies for its activities. Any type of declaratory relief concerning unidentified investigations not at issue in this litigation is without basis. *See* U.S. Const. art. III, § 2, cl. 1.

CONCLUSION

Plaintiffs respectfully request that the Court vacate and set aside the Final Rule, or in the alternative, enter a preliminary injunction pending resolution of Plaintiffs’ claims on the merits.

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